

SEAL'S COURTS
DISTRICT OF TEXAS

NOV 24 2009

Clerk of Court

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF TEXAS

UNITED STATES OF AMERICA
ex rel. John King & Jane Doe
and John King & Jane Doe,
Individually

STATE OF ILLINOIS, *ex rel.*
John King & Jane Doe;
STATE OF CALIFORNIA, *ex rel.*
John King & Jane Doe;
STATE OF FLORIDA *ex rel.*
John King & Jane Doe;
STATE OF TENNESSEE *ex rel.*
John King & Jane Doe;
STATE OF TEXAS *ex rel.*
John King & Jane Doe;
COMMONWEALTH OF MASSACHUSETTS
ex rel. John King & Jane Doe;
STATE OF DELAWARE *ex rel.*
John King & Jane Doe;
STATE OF NEVADA *ex rel.*
John King & Jane Doe;
STATE OF LOUISIANA *ex rel.*
John King & Jane Doe;
STATE OF HAWAII *ex rel.*
John King & Jane Doe;
DISTRICT OF COLUMBIA *ex rel.*
John King & Jane Doe;
COMMONWEALTH OF VIRGINIA *ex rel.*
John King & Jane Doe
STATE OF GEORGIA *ex rel.*
John King & Jane Doe;
STATE OF INDIANA, *ex rel.*
John King & Jane Doe;
STATE OF MICHIGAN *ex rel.*
John King & Jane Doe;
STATE OF MONTANA *ex rel.*
John King & Jane Doe;
STATE OF NEW HAMPSHIRE *ex rel.*
John King & Jane Doe;
STATE OF NEW JERSEY *ex rel.*
John King & Jane Doe;

CIVIL ACTION NO. 06-2662
TRANSFERRED FROM
EASTERN DISTRICT OF
PENNSYLVANIA
CIVIL ACTION NO. 03-3561

FILED UNDER SEAL

PLAINTIFF'S SECOND AMENDED
COMPLAINT PURSUANT
TO 31 U.S.C. §§ 3729-3732,
FEDERAL FALSE CLAIMS
ACT AND VARIOUS STATE
FALSE CLAIMS ACTS, AND
PENDENT STATE CLAIMS

JURY TRIAL DEMAND

STATE OF NEW MEXICO <i>ex rel.</i>	§
John King & Jane Doe;	§
STATE OF NEW YORK <i>ex rel.</i>	§
John King & Jane Doe;	§
STATE OF OKLAHOMA <i>ex rel.</i>	§
John King & Jane Doe;	§
STATE OF RHODE ISLAND <i>ex rel.</i>	§
John King & Jane Doe;	§
STATE OF WISCONSIN <i>ex rel.</i>	§
John King & Jane Doe;	§
	§
Plaintiffs,	§
	§
VS.	§
	§
SOLVAY S.A.,	§
SOLVAY AMERICA, INC.,	§
SOLVAY PHARMACEUTICALS, INC.,	§
SOLVAY NORTH AMERICA, LLC, and	§
SOLVAY PHARMACEUTICALS SARL	§
	§
Defendants.	§

PLAINTIFFS' SECOND AMENDED COMPLAINT

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TO THE HONORABLE JUDGE OF SAID COURT:

1. The United States of America, the States of California, Delaware, Florida, Georgia, Hawaii, Illinois, Indiana, Louisiana, Michigan, Montana, Nevada, New Hampshire, New Jersey, New Mexico, New York, Oklahoma, Rhode Island, Tennessee, Texas, and Wisconsin, the Commonwealths of Massachusetts and Virginia, and the District of Columbia, by and through qui tam Relators John King and Jane Doe, bring this action under 31 U.S.C. §§ 3729–3732 (the “False Claims Act”) to recover all damages, penalties and other remedies established by the False Claims Act on behalf of the United States and themselves and would show the following:

I. INTRODUCTION

2. This suit concerns rampant fraud perpetrated against Medicaid, Medicare, and other federal healthcare programs through aggressive off-label marketing and kickback schemes relating to three drugs: Luvox, Aceon, and AndroGel. To expand and maintain its market share of these drugs, Solvay deliberately and deceptively marketed uses that had not been approved by the Food and Drug Administration (“FDA”), doled out kickbacks to doctors in exchange for prescriptions, and trained doctors to misstate diagnoses so that Medicaid and other federal healthcare programs would approve and pay for unapproved uses.

3. In comparison with pharmaceutical giants like Merck and Pfizer, Solvay is a company of intimate size. From 1996 to 2002 and beyond, Solvay was, through and through, from its sales force to the highest echelons of management, deeply committed to selling Luvox, Aceon, and AndroGel by means of a scheme that involved not only illegal off-label promotions, but also kickbacks and bribes. For a combined total of about fourteen years, Relators John King and Jane Doe worked as sales representatives and managers for Solvay, where they witnessed

first-hand Solvay's company-wide policies of illegal kickbacks and off-label marketing of prescription drugs. John King worked at Solvay as a sales representative, Regional Marketing Manager and District Sales Manager from 1992 until his termination in April of 2002. In these positions, he supervised sales representatives marketing Luvox, Aceon, and AndroGel. Jane Doe was employed at Solvay from 1999 until her termination in 2002 as a District Sales Manager for the Mid-South region. Based in Louisiana, she supervised sales representatives marketing Luvox, Aceon, and AndroGel, in various parts of Arkansas, Louisiana and Texas during the period at issue. In those positions, as directed by their supervisors, King and Doe enforced Solvay's policies of illegal promotion with regard to Luvox, Aceon, and AndroGel.

4. Solvay's violations of the False Claims Act fall into three categories. First, state Medicaid programs, CHAMPUS/TRICARE, CHAMPVA, Federal Employees Health Benefit Plan, AIDS Drug Assistance Programs ("ADAPs"), and other federal healthcare programs have paid claims for reimbursement for prescriptions that have arisen from illegal off-label promotion of the three drugs. In the case of AndroGel, Medicare Part D, too, has paid out funds to cover prescriptions arising from such promotion. Second, these same prescriptions were tainted by remuneration that violated the Anti-Kickback Statute. Third, Solvay caused healthcare providers to submit false claims for reimbursement of prescriptions for Aceon and AndroGel by advising physicians to misstate diagnosis codes so that Medicaid, Medicare Part D, CHAMPUS/TRICARE, CHAMPVA, Federal Employees Health Benefit Plan, ADAPs, and other federal healthcare programs would approve and pay for unapproved uses.

II. PARTIES

5. Relator John King (“King”) is a citizen of the United States and resident of the State of West Virginia.

6. Relator Jane Doe (“Doe”) is a citizen of the United States and resident of the State of Florida.

7. Defendant Solvay S.A. is a corporation incorporated in Belgium. Its principal place of business is Rue du Prince Albert 33, B-1050 Brussels—Belgium. Solvay S.A. conducts extensive business in the States of California, Delaware, Florida, Georgia, Hawaii, Illinois, Indiana, Louisiana, Michigan, Montana, Nevada, New Hampshire, New Jersey, New Mexico, New York, Oklahoma, Rhode Island, Tennessee, Texas, and Wisconsin, the Commonwealths of Massachusetts and Virginia, and the District of Columbia.

8. Defendant Solvay America, Inc. is a corporation incorporated in the state of Delaware. Its principal place of business is 3333 Richmond Avenue, Houston Texas 77098. Solvay America, Inc. is a wholly-owned subsidiary of Defendant Solvay, S.A. Solvay America, Inc. is the United States holding company for most of the North American subsidiaries of Defendant S.A., including Defendants Solvay North America, LLC. Defendant Solvay America, Inc. conducts extensive business in the States of California, Delaware, Florida, Georgia, Hawaii, Illinois, Indiana, Louisiana, Michigan, Montana, Nevada, New Hampshire, New Jersey, New Mexico, New York, Oklahoma, Rhode Island, Tennessee, Texas, and Wisconsin, the Commonwealths of Massachusetts and Virginia, and the District of Columbia. Solvay America, Inc. may be served through its registered agent, Corporation Service Company D/B/A CSC-Lawyers Inco, 211 E. 7th Street, Suite 620, Austin, Texas 78701.

9. Defendant Solvay North America, LLC is a limited liability corporation incorporated in the State of Delaware. Its principal place of business is 3333 Richmond Avenue, Houston Texas 77098. Defendant Solvay North America, LLC is a wholly-owned subsidiary of Defendant Solvay America, Inc, which in turn is a wholly-owned subsidiary of Defendant Solvay, S.A. Solvay North America, LLC oversees and coordinates the activities of Solvay S.A.'s businesses in the United States, Canada and Mexico. Solvay North America, LLC provides financial, legal, lobbying, recruiting, compliance and other services to Solvay S.A.'s businesses in North America. Defendant Solvay North America, LLC conducts extensive business in the States of California, Delaware, Florida, Georgia, Hawaii, Illinois, Indiana, Louisiana, Michigan, Montana, Nevada, New Hampshire, New Jersey, New Mexico, New York, Oklahoma, Rhode Island, Tennessee, Texas, and Wisconsin, the Commonwealths of Massachusetts and Virginia, and the District of Columbia. Solvay North America, LLC may be served through its registered agent, Corporation Service Company D/B/A CSC-Lawyers Inco, 211 E. 7th Street, Suite 620, Austin, Texas 78701.

10. Defendant Solvay Pharmaceuticals Sarl is a corporation incorporated in Luxembourg. Solvay Pharmaceuticals Sarl conducts extensive business in the States of California, Delaware, Florida, Georgia, Hawaii, Illinois, Indiana, Louisiana, Michigan, Montana, Nevada, New Hampshire, New Jersey, New Mexico, New York, Oklahoma, Rhode Island, Tennessee, Texas, and Wisconsin, the Commonwealths of Massachusetts and Virginia, and the District of Columbia.

11. Defendant Solvay Pharmaceuticals, Inc. is a corporation incorporated in the State of Georgia. Defendant Solvay Pharmaceuticals, Inc. was a wholly-owned subsidiary of Solvay

America, Inc. until sometime in 2005, when Solvay S.A. reorganized its pharmaceutical sector and created a new wholly-owned, Luxembourg-based entity, Solvay Pharmaceuticals Sarl. All of Solvay S.A.'s pharmaceutical subsidiaries became wholly-owned subsidiaries of Solvay Pharmaceuticals Sarl, which in turn is wholly-owned by Solvay S.A. Defendant Solvay Pharmaceuticals, Inc. conducts extensive business in the States of California, Delaware, Florida, Georgia, Hawaii, Illinois, Indiana, Louisiana, Michigan, Montana, Nevada, New Hampshire, New Jersey, New Mexico, New York, Oklahoma, Rhode Island, Tennessee, Texas, and Wisconsin, the Commonwealths of Massachusetts and Virginia, and the District of Columbia. Solvay may be served through its registered agent, CT Corporations Systems, 1201 Peachtree Street, NE, Atlanta, Georgia, 30361.

III. RESPONDEAT SUPERIOR AND VICARIOUS LIABILITY

12. All defendants referred to in paragraphs seven through eleven are hereinafter referred to collectively as "Solvay" or "Defendants." Any and all acts alleged herein to have been committed by any or all of the Defendants were committed by said Defendants' officers, directors, employees, representatives or agents who at all times acted on behalf of their respective Defendant(s) and within the course and scope of their employment.

13. The Defendants identified in paragraphs seven through nine are related entities sharing common employees, offices and business names such that they are joint and severally liable under legal theories of respondeat superior. Further, the past, present and continuing relations and dealings by and between these related entities are so inextricably intertwined that for purposes of this suit, some or all of them can and should be considered as a single entity at law and equity.

IV. JURISDICTION AND VENUE

14. Jurisdiction and venue are proper in this Court pursuant to the False Claims Act (31 U.S.C. § 3732(a)) because Relators' claims seek remedies on behalf of the United States for multiple violations of 31 U.S.C. § 3729 in the United States by all or any one of Defendants, some of which occurred in the Southern District of Texas, and because all or any one of Defendants transact other business within the Southern District of Texas.

15. All defendants are subject to the general and specific personal jurisdiction of this Court. Solvay S.A. is a large multinational group of companies, which engages in a variety of business activities, including developing, marketing, and selling pharmaceutical products, all of which it accomplishes through its operating groups, subsidiaries, officers, directors, employees, and agents. Solvay S.A. contains both operating groups and regional companies, for the most part generally organized by location, including companies operating throughout the United States. The functions of these operating groups and regional companies overlap. In addition, some members of the Executive Committee for Solvay S.A. based in Belgium are also directors, officers or board members of Solvay S.A.'s subsidiaries. For example, Jacques Levy Morelle is the Vice Chairman of the Board of Directors for Solvay America, but is also the Group Corporate Secretary for Solvay S.A. Alois Michielson, the Chairman of the Board of Directors for Solvay S.A., shares the Vice Chairmanship of the Board of Directors for Solvay America with Mr. Morelle. Solvay S.A.'s executive management make a practice of visiting its American subsidiaries. As a result of Solvay S.A.'s organizational structure, Solvay S.A. and Solvay Pharmaceutical Sarl have continuous and systematic contacts with the United States through its contacts with its American subsidiaries.

16. Furthermore, Solvay Pharmaceuticals, Inc. is or has been a mere instrumentality of Solvay North America, LLC, Solvay America, Inc., Solvay Pharmaceuticals Sarl and Solvay S.A.; without it the other defendants would have been forced to perform its services themselves. In particular, Solvay S.A. and Solvay America, Inc. have exerted control over Solvay Pharmaceuticals, Inc. For example, District Sales Managers of Solvay Pharmaceuticals, Inc. were briefed on Solvay S.A.'s business strategy as part of their yearly training. In addition, at least until 2002, Solvay Pharmaceuticals, Inc.'s travel and entertainment corporate procedure required its employees, when traveling to Europe, to have the Solvay S.A. contact for the meeting arrange their hotel stays, as Solvay S.A. had negotiated rates at particular European hotels. This same travel and entertainment procedure required Solvay Pharmaceuticals, Inc. employees to obtain approval for airplane chartering and purchase of any club memberships or season tickets from Solvay America, Inc. In addition, this procedure stated that mileage reimbursement for employees was set by the Vice President of Human Resources for Solvay America, Inc. Solvay America, Inc. also provided insurance coverage to Solvay Pharmaceuticals, Inc. at least until 2002. Finally, upon information and belief, Solvay Pharmaceuticals, Inc. executive management communicated frequently with Solvay America, Inc. and Solvay S.A. executive management on business issues, including marketing campaigns for drugs and other business strategies.

V. STATUTORY AND REGULATORY BACKGROUND

A. The FDA's Role in the Regulation of Prescription Drugs

i. FDA Approval of Prescription Drugs

17. The FDA regulates human use of pharmaceutical drugs such as Aceon, Luvox, and AndroGel. Companies seeking to introduce new drugs for human use into interstate

commerce must comply with FDA statutes and regulations, such as the Federal Food, Drug and Cosmetic Act (“FDCA”). 21 U.S.C. § 301, *et seq.* Notably, the FDCA prohibits companies from distributing in interstate commerce any drugs that the FDA has not approved as safe and effective. 21 U.S.C. § 355(a) and (b).

18. In order for a company to gain approval of a drug by the FDA, the company must first submit and receive approval of a New Drug Application (“NDA”) pursuant to 21 U.S.C. § 355. The company is required to include in its NDA all intended uses proposed for a new drug’s labeling and to prove that the new drug is safe and effective for those uses. 21 U.S.C. § 355(b). To prove that the drug is safe and effective, the company must provide the FDA with data from scientifically sound clinical trials. The FDA will refuse approval of a new drug unless, on the basis of all information reviewed, it is demonstrated that a drug can safely accomplish its purported effect under the conditions proposed, and that the method of manufacture and distribution will properly preserve the drug for this purpose. 21 U.S.C. § 355(d).

19. In 1983, Congress passed the Orphan Drug Act to promote the development of pharmaceutical drugs for people with rare diseases or medical conditions by providing drug manufacturers with incentives, such as FDA funding of the clinical trials necessary for drug approval, certain tax breaks for expenses incurred in developing an orphan drug, and a seven-year period of marketing exclusivity to the first drug manufacturer to obtain FDA approval of the designated orphan drug. *See* Orphan Drug Act of 1983, Pub. L. No. 97-414, 96 Stat. 2049 (1983), codified at 21 U.S.C. §§ 360aa-360dd. Under the Orphan Drug Act, the FDA is required – to grant orphan drug designation if the sponsor shows a “medically plausible basis for expecting the drug to be effective in the prevention, diagnosis, or treatment of that disease or condition.”

21 C.F.R. § 316.25(a)(2). The fact that a drug has been designated as an orphan drug under the Orphan Drug Act does *not* mean that the drug is FDA-approved for the treatment of that indication. Solvay obtained an orphan drug designation to research the use of AndroGel in treating wasting in patients diagnosed with Acquired Immunodeficiency Syndrome (“AIDS”) and Human Immunodeficiency Virus (“HIV”). It never received FDA approval for this use, however, and thus this was an off-label use.

ii. FDA Regulation of Manufacturers’ Marketing of Prescription Drugs

20. When the FDA reviews an NDA and approves a drug for interstate distribution, that approval is only effective for the intended uses that were proposed in the NDA and described on the drug’s approved label. Any use for a drug that was not proposed in the NDA and approved for the label by the FDA is referred to as “unapproved” or “off-label.” 65 Fed. Reg. 14286, 14286 (Mar. 16, 2000). Off-label use also includes the use of a drug granted orphan drug status under the Orphan Drug Act. Although physicians traditionally may prescribe a drug for an off-label use so long as the drug has been FDA-approved for some use, pharmaceutical companies are strictly prohibited from marketing a drug for an off-label use.

21. When a company markets a drug off-label, the drug becomes a new drug for that purpose and is considered “misbranded” in violation of 21 U.S.C. § 331; 21 U.S.C. § 352(f); 21 C.F.R. § 310.3 (h)(4) and (5); 65 Fed. Reg. 14286, 14286 (Mar. 16, 2000) (“[A]n approved new drug that is marketed for a ‘new use’ is also ‘misbranded’ under the FDCA, because the labeling of such a drug would not include ‘adequate directions for use.’”). Section 352 of title 21 of the United States Code lists situations in which a drug is illegally misbranded, including but not limited to situations where: (1) the drug’s labeling is “false or misleading in any particular;” (2)

the drug's labeling does not bear adequate direction for use; or (3) the drug's labeling does not bear "adequate warnings against use in those pathological conditions or by children where its use may be dangerous to health, or against unsafe dosage or methods or duration of administration or application, in such manner and form, as are necessary for the protection of users" See 21 U.S.C. § 352(a) and (f).

22. The term "labeling" encompasses the actual label attached to the drug's immediate container, as well as all "other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article." 21 C.F.R. § 321(m). The term has been construed to include a variety of drug company promotional materials, including booklets, pamphlets, and literature that is textually related to the product, even when disseminated without the presence of the drug. See *Kordel v. United States*, 335 U.S. 345, 349 (1948); *V.E. Irons, Inc. v. United States*, 244 F.2d 34, 39 (1st Cir. 1957). In determining if a drug's labeling or advertising is misleading and thus misbranded, one must examine "(among other things) not only representations made or suggested by statement, word, design, device, or any combination thereof, but also the extent to which the labeling or advertising fails to reveal facts material in the light of such representations or material with respect to consequences which may result from the use of the article" as described by the labeling or advertising or the customary or usual use of the article. 21 U.S.C. § 321(n).

23. In order for a drug's labeling to include "adequate directions for use," the directions must allow a layman to use the drug safely and for its "intended use." See 21 C.F.R. § 201.5. The "intended use" of a drug refers to "the objective intent of the person legally responsible for the labeling of drugs." See 21 C.F.R. § 201.128. "The intent is determined by

such persons' expressions or may be shown by the circumstances surrounding the distribution of the article," and "may, for example, be shown by labeling claims, advertising matter, or oral or written statements by such persons or their representatives." *Id.* Thus, if a manufacturer promotes a drug for a use for which the label does not provide adequate directions for use or is otherwise false and misleading, misbranding has occurred, regardless of Medicaid or Medicare Part D's reimbursement of the drug for this use.

24. Over the years, the FDA has issued regulatory guidances to aid manufacturers in distinguishing between these illegal marketing strategies and legitimate non-promotional dissemination of information on off-label uses, by setting forth factors to determine whether a manufacturer's dissemination of information is actually promotional. These guidances make it clear that pharmaceutical manufacturers cannot use reprints, reference texts or Continuing Medical Education ("CME") programs as tools to promote off-label uses. *See* Guidance to Industry on Dissemination of Reprints of Certain Published, Original Data, 61 Fed. Reg. 52800 (Oct. 8, 1996); Guidance for Industry Funded Dissemination of Reference Texts, 61 Fed. Reg. 52800 (Oct. 8, 1996); Final Guidance on Industry-Supported Scientific and Educational Activities, 62 Fed. Reg. 64074 (Dec. 3, 1997); Guidance for the Industry: Good Reprint Practices for the Distribution of Medical Journal Articles and Medical or Scientific Reference Publications on Unapproved New Uses of Approved Drugs and Approved or Cleared Medical Devices, 74 Fed. Reg. 1694-01 (Jan. 13, 2009). None of these guidances have changed the FDA's long-standing prohibition against marketing and promoting approved drugs for off-label uses.

B. Reimbursement of Prescription Drugs under Medicaid, Medicare Part D, CHAMPUS/TRICARE, CHAMPVA, Federal Employee Health Benefit Plan, ADAPs, and Other Federal Healthcare Programs

i. Medicaid

25. Medicaid was established by Title XIX of the Federal Social Security Act, 42 U.S.C. § 1396 *et seq.* (the “Medicaid Program”). Medicaid is a joint federal-state program that provides health care benefits for certain groups, primarily the poor and disabled. In addition to meeting the FDA drug **approval requirements**, Solvay applied for and received Medicaid coverage for the three drugs in each of the fifty states, including the States of California, Delaware, Florida, Georgia, Hawaii, Illinois, Indiana, Louisiana, Michigan, Montana, Nevada, New Hampshire, New Jersey, New Mexico, New York, Oklahoma, Rhode Island, Tennessee, Texas, and Wisconsin, the Commonwealths of Massachusetts and Virginia, and the District of Columbia.

26. The federal Medicaid statute sets forth the minimum requirements for state Medicaid programs to qualify for federal funding. *See* 42 U.S.C. § 1396a. The federal portion of states’ Medicaid payments, known as the Federal Medical Assistance Percentage (“FMAP”), is based on a state’s per capita income compared to the national average. 42 U.S.C. § 1396d(b). States’ FMAPs range between 50% and 83%.

a. Drug Coverage under Medicaid

27. As a general rule, to be reimbursable under a state’s Medicaid program, a drug must be included on the state’s formulary. Each state has its own means of deciding coverage, but federal law sets forth requirements states must meet in excluding or restricting coverage. *See* 42 U.S.C. § 1396r-8. A state may exclude or restrict coverage of a drug in four instances:

- (1) the prescribed use is not for a medically accepted indication;
- (2) the drug is on a list of drugs excluded by the state from Medicaid coverage;
- (3) the drug manufacturer agreed to the restrictions on the drug in its rebate agreement with Medicaid; or
- (4) the drug was excluded from the state’s drug formulary.

31 U.S.C. § 1396r-8(d)(1). In addition, states may use prior authorization programs or preferred drug lists to control potential abuses of drugs, such as prescriptions for an indication that is not a medically accepted indication.

28. A “medically accepted indication” is a use that is listed in the labeling approved by the FDA or “the use of which is supported by one or more citations included or approved for inclusion in” one of the drug compendia identified by the Medicaid statute. 42 U.S.C. § 1396r-8(k)(6). These compendia are the American Hospital Formulary Service Drug Information, the United States Pharmacopeia-Drug Information (or its successor publications), and the DRUGDEX Information System. 42 U.S.C. § 1396r-8(g)(1)(B)(i). The United States Government and the states interpret “supported by” to require “some form of corroboration or validation.” United States’ Statement of Interest in Response to Defendant’s Motion to Dismiss Plaintiff’s First Amended Complaint, *United States ex rel. Rost v. Pfizer, Inc.*, 03-CV-11084, at p. 5 (May 16, 2008); *see also* Centers for Medicare and Medicaid Release No. 141 (May 4, 2006) (“The statute requires coverage of off-label uses of FDA-approved drugs for indications that are supported (as opposed to listed) in the compendia specified in section 1927(g)(1)(B)(II).”).

b. Role of Prior Authorization and ICD-9 Coding in Drug Reimbursement

29. Most states require prior authorization for drugs that are not listed on their preferred drug lists. For example, New Hampshire requires prior authorization for Aceon, which is a non-preferred drug in that state. Some states require prior authorization for certain drugs even if they are on the preferred drug list. To obtain prior authorization, and consequently Medicaid coverage for a drug requiring prior authorization, most states require a physician to

allege that the drug is required because one of the following criteria exist: 1) a treatment failure with a preferred drug; 2) a contraindication to preferred drugs; or 3) an allergic reaction to a preferred drug. Some states' prior authorization forms also require a physician to certify that the drug is medically justified or that the information on the form is accurate and complete. Physicians are also required to list the patient's diagnosis, either written out or by using ICD-9 Codes (International Coding Diagnoses Codes, 9th revision)—a coding system used by Medicaid to numerically designate a diagnosis, or diagnoses, for patients. Upon information and belief, certain state Medicaid programs will reimburse for pharmaceutical drugs only if the drug corresponds with a specific diagnosis of the patient, designated by an ICD-9 code recorded by the patient's physician.

30. All three of Solvay's drugs involved in this case (Luvox, Aceon, and AndroGel) require prior approval in some states. All three drugs were promoted for off-label uses, including many uses that are not eligible for reimbursement because they appear in no approved compendium.

ii. Medicare Part D

31. Medicare Part D is a federal program meant to subsidize the costs of prescription drugs for Medicare beneficiaries. It was enacted as part of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 and went into effect on January 1, 2006. Part D only covers prescription drugs and will not assist with any other medical procedure (i.e. X-rays, doctor visits, etc.). Among those individuals eligible for Medicare Part D are individuals with dual-eligibility, i.e., beneficiaries enrolled in both Medicare and Medicaid, who prior to 2006 had received outpatient drug benefits through Medicaid. Although Medicare Part D is a component of Medicare, each of the fifty states and the District of Columbia are required to make a

contribution to the United States government to defray a portion of the cost of Medicare Part D for beneficiaries whose Medicaid drug coverage has been assumed by Medicare Part D. 42 C.F.R. § 423.910(a) (2008).

32. A Medicare beneficiary enrolled in Medicare Part D chooses a Prescription Drug Plan (PDP), which is administered by a private insurance company, or “sponsor,” based upon the beneficiary’s specific drug requirements. Part D sponsors are required by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 to offer, at a minimum, a basic prescription drug benefit that is either the standard prescription drug benefit or is actuarially equivalent to the standard benefit. The standard costs structure makes beneficiaries responsible for certain costs, which may include a monthly premium, an annual deductible, and coinsurance.

33. In 2008, for example, the standard drug benefit had a beneficiary deductible of \$275. In the initial phase of the Part D benefit, after beneficiaries paid the deductible, they contributed 25 percent coinsurance toward their drug costs and the plan paid the remaining 75 percent until combined beneficiary and plan payments reached \$2,510. After combined payments reached \$2,510, beneficiaries entered the coverage gap phase of the benefit, or “donut-hole,” in which they were responsible for 100 percent of their drug costs. The catastrophic coverage phase began when a beneficiary’s out-of-pocket costs reached \$4,050. This amount included a beneficiary’s deductible and coinsurance payments. Once beneficiaries reached \$4,050 in out-of-pocket costs, they contributed approximately 5 percent in coinsurance toward their drug costs. Of the remaining 95 percent of drug costs, the Part D sponsors are responsible for approximately 15 percent while Medicare pays 80 percent.

34. Before the beginning of the plan year, sponsors are required to submit a bid for each plan that they intend to offer. The bid is an estimate of the average costs to provide the basic benefit per beneficiary. Throughout the year, the Centers for Medicare & Medicaid Services (CMS) makes prospective payments to sponsors for three subsidies based on sponsors' approved bids. These subsidies are: (1) the direct subsidy, (2) the reinsurance subsidy, and (3) the low-income cost-sharing subsidy. The direct subsidy, together with beneficiary premiums, is designed to cover the sponsor's cost of providing the benefit to each beneficiary. The reinsurance subsidy covers the Federal Government's share of drug costs for beneficiaries who have reached catastrophic coverage. The low-income cost-sharing subsidy covers the Federal Government's portion of the cost-sharing payments for certain low-income beneficiaries. At the end of the plan year, CMS reconciles these prospective payments with the actual costs incurred by the plan sponsors.

35. All Part D plan sponsors submit data and information necessary for CMS to determine and make payment. Every time a beneficiary fills a prescription covered under Part D, plan sponsors must submit a summary called the prescription drug event (PDE) record. The PDE record contains drug cost and payment data that enable CMS to administer the Part D benefit. Part D plan sponsors submit one PDE record each time a Part D covered drug is dispensed to its enrollees, even for those events in which enrollees have 100 percent cost sharing (i.e., they are in the coverage gap or deductible phase).

36. CMS uses the National Council for Prescription Drug Programs industry standard for collecting PDE data. The PDE data contain information on the beneficiary, plan, pharmacy, and prescribing physician, as well as information about the event, including the date, quantity

dispensed, number of days supplied, national drug code, control number, and the amount reimbursed to the pharmacy by the plan.

37. Part D covered drugs are defined as drugs available only by prescription, which are used and sold in the United States and used for a medically accepted indication, biological products, insulin and vaccines. *See* 42 C.F.R. § 423.100. Medicare Part D's definition of a "medically accepted indication" is the same as Medicaid's: it is a use that is approved under the Federal Food, Drug, and Cosmetic Act, or "is supported by one or more citations included or approved for inclusion in" one of the drug compendia identified by the Medicaid statute (i.e., American Hospital Formulary Service Drug Information, DRUGDEX, and United States Pharmacopeia-Drug Information (or its successor publications)). *See* 42 C.F.R. § 423.100, 42 U.S.C. §§ 1396r-8 (g)(1)(B)(i) and (k)(6). As stated above, the United States Government interprets "supported by" to require "some form of corroboration or validation." United States' Statement of Interest in Response to Defendant's Motion to Dismiss Plaintiff's First Amended Complaint, *United States ex rel. Rost v. Pfizer, Inc.*, 03-CV-11084, at p. 5 (May 16, 2008); *see also* Centers for Medicare and Medicaid Release No. 141 (May 4, 2006) ("The statute requires coverage of off-label uses of FDA-approved drugs for indications that are supported (as opposed to listed) in the compendia specified in section 1927(g)(1)(B)(II).").

38. Part D sponsors are responsible for ensuring that covered Part D drugs are prescribed for "medically accepted indications." Some Part D sponsors use prior authorization programs to ensure drugs are being used for medically-accepted indications. AndroGel is commonly listed on PDP formularies for Medicare Part D and is reimbursable under many Medicare Part D plans across the country.

iii. CHAMPUS/TRICARE, CHAMPVA, Federal Employee Health Benefit Plan, and ADAPs

39. In addition to Medicaid and Medicare Part D, the federal and state governments reimburse a portion of the cost of prescription drugs under several other federal and state health care programs, including but not limited to CHAMPUS/TRICARE, CHAMPVA, Federal Employees Health Benefit Plan, and ADAPs.

40. The Civilian Health and Medical Program of the Uniformed Services (“CHAMPUS”) and TRICARE, a continuation of CHAMPUS, are federally funded uniformed services health care programs for active duty and retired service members, members of the National Guard and Reserve, service members’ families, survivors of service members, and certain former spouses of service members. The Civilian Health and Medical Program of the Department of Veterans Affairs (“CHAMPVA”), is a federally funded healthcare program for the families and survivors of veterans who have been rated permanently and totally disabled for a service-connected disability and for the survivors of a military member who died in the line of duty, not due to misconduct. The Federal Employees Health Benefit Plan is administered by the Office of Personnel Management and provides health insurance for federal employees, retirees, and survivors. Coverage of prescription drugs under these programs is similar to coverage under the Medicaid program. *See, e.g.*, 32 C.F.R. §§ 199.2 and 199.4(g)(15)(i); TRICARE Policy Manual 6010.54-M, Chapter 8, Section 9.1(B)(2) (August 2002); CHAMPVA Policy Manual, Chapter 2, Section 22.1, Art. II.

41. Title II of the Ryan White Comprehensive AIDS Resources Emergency Act (the “CARE Act”) authorizes the creation of state AIDS Drug Assistance Programs (“ADAPs”). ADAP is a federal program that allows for an expansion of Medicare and Medicaid coverage. In

addition to allowing states to create their own programs, ADAP provides more federal funding for states to expand eligibility to include a greater number of AIDS victims and ensure that HIV-positive uninsured and under-insured individuals have access to pharmaceutical (drug) therapies. The goal of ADAP is to make available drug treatments that can reliably be expected to increase the duration and quality of life of people living with HIV, while ensuring that ADAP is used only after all other potential payer options are exhausted. Coverage of prescription drugs under ADAPs is the same as Medicaid. *See* Veterans' Health Care Act of 1992, Pub. L. No. 102-585, § 602 (November 1992).

C. Prohibition of Kickbacks Associated with Medicaid, Medicare, CHAMPUS/TRICARE, CHAMPVA, Federal Employee Health Benefit Plan, and ADAPs Prescriptions

i. Federal Anti-Kickback Statute

42. The Medicare-Medicaid Anti-Fraud and Abuse Amendments, known as the Medicare Anti-Kickback Statute (the "Anti-Kickback Statute"), 42 U.S.C. § 1320a-7b(b), make it illegal for an individual knowingly and willfully to offer or pay remuneration in cash or in kind to induce a physician to order a good or service that is reimbursed by a federal healthcare program. *See* 42 U.S.C. § 1320a-7b(b)(2). "Remuneration" is broadly defined to include anything of value offered or paid in return for purchasing, ordering, or recommending the purchase or order of any item reimbursable by a federal healthcare program. *See* Department of Health and Human Services, Office of Inspector General Compliance Program Guidance for Pharmaceutical Manufacturers, 68 Fed. Reg. 23731, 23734, 23737 (May 5, 2003).

43. The purpose of the Anti-Kickback Statute is to prohibit such remuneration in order to secure proper medical treatment and referrals and to limit unnecessary treatment, services, or goods that are based not on the needs of the patient but on improper incentives given

to others, thereby limiting the patient's right to choose proper medical care and services. *See* Medicare and Medicaid Programs; Fraud and Abuse OIG Anti-Kickback Provisions, 54 Fed. Reg. 3088, 3089 (proposed Jan. 23, 1989) (to be codified 42 C.F.R. pt. 1001) (“[I]t is necessary for the fiscal integrity of the Medicare and Medicaid programs to assure that physicians exercise sound, objective medical judgment when controlling admittance [of new drugs and medical devices] to . . .” the medical marketplace.).

44. Paying kickbacks taints an entire prescription, regardless of the medical propriety of its use. The kickback inherently interferes with the doctor-patient relationship and creates a conflict of interest, potentially putting the patient's health at risk. Any defendant convicted under the statute is automatically barred from participating in federal and federally-funded healthcare programs.

ii. **OIG, PhRMA, AMA and ACCME's Guidelines on the Manufacturer-Doctor Relationship and Behaviors that Violate the Anti-Kickback Statute**

45. Recognizing that the Anti-Kickback Statute has been applied broadly, the OIG has acknowledged that liability under the statute will ultimately turn on intent. *See* Department of Health and Human Services, Office of Inspector General (“OIG”) Compliance Program Guidance for Pharmaceutical Manufacturers, 68 Fed. Reg. 23731 (May 5, 2003). In order to assist pharmaceutical manufacturers, the OIG issued a guidance in May 2003 that not only stated its interpretation of the Anti-Kickback statute, but also highlighted activities that may give rise to liability under the statute. *See id.* The OIG Guidance also directed drug manufacturers to review the PhRMA Code, the ACCME standards relating to CMEs, and an ethical opinion issued in June 1992 and amended in April 2001 by the AMA stating its guidelines to govern doctors' acceptance of gifts from pharmaceutical manufacturers. *See* AMA Opinion 8.061 (1992,

amended 2001); PhRMA Code (2003); ACCME Standards (2004). All of these industry guidelines draw plain lines of demarcation for acceptable and unacceptable behavior under the Anti-Kickback statute.

46. The OIG's Guidance addressed specific practices commonly arising in the relationship between a drug manufacturer and physicians that present problems. *Id.* at 23738. Of particular concern to the OIG were "preceptorships," educational and research funding, CMEs, consulting and advisory arrangements, and gifts of more than trivial value to physicians, such as entertainment, recreation, travel, and meals. *Id.* The OIG was also concerned about payments to physicians to: 1) listen to sales representatives market their drugs, 2) access marketing web sites, or 3) perform "research" for drug manufacturers. *Id.*

47. The AMA, PhRMA and ACCME guidelines have suggested similar limits on pharmaceutical activities. Where the three guidelines share the same perspectives on improper activities, one can presume these activities are likely to violate the federal Anti-Kickback statute.¹

48. The issuance of these guidelines by the OIG, AMA, PhRMA and ACCME, in addition to the enactment of the Anti-Kickback Statute itself, demonstrates that federal and state health care programs consider compliance with the Anti-Kickback Statute a prerequisite to receiving or retaining reimbursement payments from Medicaid, Medicare Part D, and other federal health care programs.

VI. SOLVAY'S SCHEME TO SELL LUVOX, ACEON, AND ANDROGEL THROUGH OFF-LABEL MARKETING AND ILLEGAL KICKBACKS

¹ The three guidelines all address several pharmaceutical activities, such as gifts, entertainment, conferences, CMEs, and consultants. The ACCME standards address only CME activities.

A. Off-Label Marketing Strategies

49. As described below, Solvay engaged in a nationwide off-labeling scheme that not only violated the FDA prohibitions against marketing off-label uses of drugs and illegally misbranding drugs, but also violated the Anti-Kickback statute. Two of the drugs, AndroGel and Luvox, were each indicated only for one rare condition—Solvay’s promotion of these two drugs was *predominantly* off-label. The third drug, Aceon, arrived as a latecomer in an extremely crowded field, and relied on off-label claims to distinguish itself. As a result of this nationwide scheme, Solvay reaped profits far beyond those it would have achieved from legitimate promotion.

i. Luvox (Fluvoxamine)

a. History of Luvox

50. Solvay first developed Luvox in 1984 but obtained FDA approval for the drug much later, in December 1994. Unexpectedly, the FDA approved Luvox solely for the medical indication of Obsessive Compulsive Disorder (“OCD”), which is defined to involve recurrent obsessions or delusions that are severe enough to be time-consuming or cause marked distress or significant impairment.² That narrow approval was a great disappointment to the manufacturer; Solvay had expected that Luvox, an SSRI (selective serotonin reuptake inhibitor) like Prozac, would receive FDA approval for the treatment of depression.

51. Solvay’s sales force was assured that Solvay failed to obtain a depression indication for Luvox only because of what was described as a technicality: the “Cytochrome P450” side effect. Luvox, like the antihistamine Seldane, used in conjunction with certain other

² See DSM-IV Section 300.3. The DSM-IV is the fourth version of the American Psychiatric Association’s Diagnostic and Statistical Manual.

drugs, such as Xanax, affects the 3A4 pathway in the liver. Luvox inhibits the Cytochrome P450 enzyme from metabolizing substances, such as caffeine, haloperidol (Haldol), diazepam (Valium), theophylline (used to treat asthma and respiratory diseases), and alprazolam (Xanax). This inhibition can then cause the drug to accumulate in the bloodstream, potentially leading to heart arrhythmia, cardiac arrest, and even death.

52. The side effect was serious enough to strip Seldane of its FDA approval. Nevertheless, shortly after receiving the FDA's decision, Jack Redmond, Group Product Manager for the Mental Health Marketing Team, and Steve Jennings, Business Director for Cardiology and Mental Health, told the entire Mental Health sales force that the FDA was unconcerned about the Cytochrome P450 side effect and that the FDA was "thrilled" to have another SSRI on the market that could fight not only OCD but depression and other diseases, especially given Luvox's "favorable side effect profile." Redmond and Jennings assured the team that if Prozac and other SSRIs had been applying for approval only now, they would have received the same warnings and perhaps been approved for a limited indication. The sales force was encouraged to share this message with doctors, and did so.

53. As years went by, challenges to Luvox's claims of safety and efficacy mounted, casting doubt on the company's version of the reasons for denying Luvox a depression indication. The company instructed the sales force that whenever doctors challenged them on Luvox's efficacy in treating depression, representatives were to respond that further clinical data on depression was unnecessary because all SSRI's supposedly worked the same way in the body.

54. In 1997, Solvay obtained a limited approval for Luvox to treat OCD in children. Later the same year, the FDA placed Solvay on its Application Integrity Policy ("AIP") list.

Placement on the FDA's AIP list is a punitive measure that the FDA takes after learning of suspected wrongdoing regarding the application process by a company. For the period of time that a company is on the AIP list, the FDA may suspend its review of all of that company's pending product approval applications. *See* Fraud, Untrue Statements of Material Facts, Bribery, and Illegal Gratuities; Final Policy, 56 Fed. Reg. 46191 (September 10, 1991). In addition, the FDA may conduct on-site inspections and review the company's self-audits. Solvay was on the AIP list for six years, from 1997 to 2003. While Solvay could submit new and supplemental drug applications during that time, these applications were not reviewed until Solvay was removed from the list.

55. In 1999, Luvox and Solvay drew fire after the public learned that one of the teenage "Columbine killers" had been taking the drug. In June 2000, Luvox's patent exclusivity expired and sales sharply declined after multiple generics entered the market. In 2002, an FDA audit revealed possible inaccuracies in the chemistry, manufacturing and controls section of Solvay's Luvox and Rowasa³ applications. The FDA notified Solvay and offered it the opportunity to voluntarily withdraw the application for Luvox. In May 2002, Solvay withdrew its Luvox application and suspended sales of Luvox in the United States.⁴ The move coincided with the release of expert reports in civil litigation against Solvay for wrongful death stemming from the Columbine killings.

56. In March 2004, after the danger that anti-depressants can cause mania in children had become better known, the FDA requested manufacturers of generic Luvox and other SSRIs

³ Rowasa rectal suppositories are approved by FDA to treat mild to moderate distal ulcerative, colitis, proctosigmoiditis or proctitis; Rowasa is not at issue in this case.

⁴ The withdrawal of Solvay's original Luvox application became effective on September 3, 2003.

to carry stronger warnings recommending close observation of adult and pediatric patients for worsening depression or the emergence of suicidality.

57. In 2006, three years after AIP status was lifted, Solvay made plans to reintroduce a new slightly modified version of Luvox. Solvay collaborated with Elan Pharma International Limited to develop a version of Luvox (Luvox CR) that would supposedly allow the extended release of the drug over a 24-hour period. Solvay and Elan submitted a new drug application for Luvox CR to the FDA in April 2006. In January 2007, Solvay licensed the exclusive rights to the market Luvox and Luvox CR to Jazz Pharmaceuticals. In 2007, after Luvox had been off the market for five and half years, the FDA approved Solvay's new drug application for Luvox's old formulation, allowing Solvay to begin marketing the drug again. Only then did the FDA approve the drug for social anxiety disorder for adults, and until that time, Luvox has never been approved for any indication other than to treat OCD. Solvay obtained FDA approval for Luvox CR to treat OCD and social anxiety disorder in February 2008. Under the Solvay's licensing agreement with Jazz Pharmaceuticals, Jazz Pharmaceuticals paid Solvay \$20 million after it received FDA approval for Luvox CR.

b. Off-Label Marketing of Luvox

58. In 1994, few people had heard of obsessive compulsive disorder, or "OCD," Luvox's one approved indication. The disorder was estimated to occur in only 2.5% or less of the general population. Psychiatrists and primary care doctors alike rarely encountered patients suffering from "classic" OCD. Solvay acknowledged in training videos for its sales force that, "Talking about Luvox for OCD is not going to motivate our physicians to prescribe our drug into the 21st Century." Realizing that OCD alone would not provide meaningful sales, Solvay committed itself to promoting off-label uses of Luvox, such as treating depression (despite the

weak support for that indication), conditions on what Solvay called the “OC Spectrum,” panic, and anxiety. As a result of Solvay’s off-label marketing schemes for Luvox, Solvay dramatically increased its sales beyond what it would have achieved through legitimate marketing.

**(I) Depression, Anxiety, and Insomnia, and Luvox’s
Supposed Calming Effect**

59. In 1994, physicians were already well-acquainted with a class of drugs called SSRIs (selective serotonin reuptake inhibitors), typically used to treat depression. Examples of popular and profitable SSRI-type drugs include Paxil, Prozac, and Zoloft. At the time Solvay began marketing the off-label uses of Luvox, Zoloft, for instance, had generated two billion dollars in sales. Luvox, though not approved for depression, belongs chemically to the same class of drugs. Seeking to gain a portion of that profitable market share, therefore, Solvay rolled out nationwide training videos instructing its sales force that: “[Luvox] is not a compound for OCD . . . it is an SSRI and we need to present [Luvox] as an SSRI.” Solvay further urged pharmaceutical representatives in these videos to give doctors “good solid information about the drugs at [their] disposal in order to best know how to use them, *indications aside*.”

60. Just as Solvay made much of Luvox’s status as an SSRI, the company made habitual references to Luvox’s supposed long track record of use and safety in Europe, such as a March 1998 presentation that stated that the focus should be on safety when introducing Luvox to primary care physicians and pointing to “19 years of worldwide experience in over 12 million patients.” But that experience was in treating depression, a use for which the FDA had denied approval; Solvay’s claims suggested that Luvox had such an indication. Solvay nevertheless trained sales representatives to make such claims to physicians to boost confidence in the drug

and promote use for depression. Such claims were common among Solvay representatives in the field.

61. Solvay distinguished Luvox from its competitors, more successful SSRIs such as Paxil, Prozac and Zoloft, by telling doctors that Luvox had all of the benefits of these more popular drugs, a superior side effect profile, and a “calming effect.” These kinds of allegations of superiority are rarely supported by a drug’s FDA-approved label, and Luvox is no exception.

62. Yet Luvox’s so-called calming effect was also the basis for Solvay’s off-label promotion of the drug for both stand-alone anxiety and depression accompanied by symptoms of anxiety. Solvay also promoted Luvox as a substitute drug for the treatment of anxiety, another use not cited in any of the drug compendia. Relator John King helped to develop the promotion of Luvox for depression with anxiety disorder at the urging of Solvay management, who were still reeling from the FDA’s refusal to approve the drug for depression. King incorporated the claim into a 1999 presentation used for training sales representatives, to promote Luvox to primary care physicians, which the company utilized nationwide. No scientific evidence inspired the claim, and none supported it. Luvox’s initial “calming effect” or tendency to induce somnolence, compared with other anti-depressants, formed the sole basis for this promotion.

63. The presentation noted that doctors usually use a combination of an SSRI and a benzodiazepine, such as Xanax or Valium, to treat depression-related anxiety. Solvay sales representatives should suggest, the presentation urged, that Luvox alone could achieve the effect of a treatment with an SSRI and a benzodiazepine with just one drug rather than two. Further, the presentation suggested that Luvox was a superior choice for anxiety because it was not addictive like benzodiazepines.

64. The presentation also offered a regimen for switching patients from their current SSRI and benzodiazepine to Luvox only; no doctor or scientist was consulted in creating this titration method. Specifically, sales representatives were directed to tell doctors to stop the current SSRI and wait one week before beginning Luvox. After starting Luvox, the doctor could taper the patient's benzodiazepine usage. This shift in medication had the potential to cause a patient to begin a downward decline into depression and experience higher than usual anxiety, as the patient was taken off drugs that were known to work and put on Luvox, a drug that Solvay knew did not treat anxiety. The patient might then require further doctor's visits to correct the problem, with further risks and expenses being the inevitable result.

65. Solvay's management showed this training presentation at training seminars nationwide and expected sales representatives to use its pitch to promote Luvox to primary care physicians. King was rewarded for the presentation through bonuses and the presentation is discussed as among his achievements in his 1999 annual evaluation.

66. Solvay capitalized on Luvox's supposed calming effect by promoting yet another off-label use: Luvox as a sleep aide. King's 1999 presentation, adopted and distributed nationwide, urges such promotion, and call notes reflect such discussions with physicians. The use has never been listed in a drug compendium.

67. While depression and depression accompanied by anxiety are listed in DRUGDEX, sometime between 2003 and 2008, DRUGDEX's authors, though listing the same research, downgraded depression from its most supportive category into a middle range, with the strength of the recommendation now only "in some cases." Moreover, the FDA specifically

rejected the new drug application submitted for depression. Stand-alone anxiety disorder, conversely, has never been listed in a drug compendium.

(II) OC Spectrum

68. Even before launch, Solvay attempted to expand Luvox sales beyond its narrow indication by promoting to physicians, the FDA, drug compendia, Medicaid agencies, and the medical community at large the concept of the “Obsessive Compulsive Spectrum” (“OC Spectrum”). The OC Spectrum hypothesis rests on the controversial premise that a whole host of disorders that arguably involve obsessions or compulsions can somehow be considered related and even treated with the same drug regimen. Because Luvox is safe and effective for OCD, the logic goes, it must be safe and effective for a wide *spectrum* of diverse non-approved disorders, such as: attention deficit hyperactivity disorder (ADHD), autism, anorexia, bulimia, irritable bowel syndrome, Tourette’s syndrome, kleptomania, panic disorder, post-traumatic stress disorder (PTSD), body dysmorphic disorder, hypochondriasis, migraines, compulsive eating, gambling, social phobias,⁵ nervousness, trichotillomania, compulsive buying, and agitation, among others.

69. Documents from immediately after launch reflect Solvay’s companywide initiative to pursue “OC Spectrum” sales. A Spring 1996 training video featuring Jack Redmond, Group Product Manager of the Mental Health Marketing Team, circulated to the sales force and senior management, broadcast that Solvay’s sales force **had** already expanded the definition of OCD under the broader umbrella of anxiety disorder **symptoms**, allowing for a new focused product message to capitalize on the market for treatment of patients with symptoms of obsessions and compulsions.

⁵ Over ten years later, social anxiety disorder approved by the FDA for adults only.

70. Some Plan of Action (POA) Brand Data sheets for Luvox have explicitly incorporated specific sales goals in this off-label sector. Indeed, the sales force was expected in some years to grow sales *primarily* through pursuing OC Spectrum prescriptions.

71. Solvay's sales force made remarkable inroads with primary care physicians who had less experience than specialists with psychotropic drugs and tended to refer out difficult mental health cases. These doctors were often reluctant to treat "classic" OCD patients suffering from behaviors like checking and compulsive washing of hands, because of the complexity of the disease state and the tenacity of its symptoms. At nationwide trainings and in the field, primary care sales representatives were told to avoid referring to "OCD," which denotes a strange and rare disease state, and to instead use the phrase "OC Spectrum" and discuss "obsessions" and "compulsions" in communicating with physicians. They concentrated on "obsessive and compulsive symptoms" rather than indications. Sales representatives urged physicians to recognize, not "classic" OCD, but milder obsessive and compulsive symptoms, in many of the patients whom they see daily, such as the hypochondriacs who frequent any primary care practice. Solvay's sales force was instructed that once defined this loosely, "obsessive and compulsive symptoms" affected as much as ten percent of the general population. Through CMEs, promotional speakers, and their own sales pitches, sales representatives presented Luvox as a one-size-fits-all cure for such symptoms. The result was an explosion of scripts nationwide, few of them on-label.

72. Scant scientific evidence exists to support these non-approved, off-label uses. In fact, many of the discussions of the OC Spectrum concept that exist in medical literature have

criticized it. Not all disorders involving compulsions, for instance, have a similar source, nor do they necessarily function similarly.

73. Of the “OC Spectrum” disorders listed above, DRUGDEX has never listed nervousness, ADHD, or agitation. It lists compulsive buying, but as “not recommended.” Migraines, Tourette’s syndrome, kleptomania, and irritable bowel syndrome were actually completely delisted from DRUGDEX between 2003 and 2008, apparently because of concerns about the listings. PTSD, autism, body dysmorphic disorder, panic disorder, and eating disorders were all downgraded on DRUGDEX sometime between 2003 and 2008. Only social anxiety disorder is recommended, and hypochondriasis, compulsive gambling, and trichotillomania all fall under DRUGDEX’s middle category. While the studies in DRUGDEX in support of off-label uses are varied in terms of sponsorship, the studies cited under OC Spectrum uses were largely sponsored by Solvay or Solvay-owned subsidiaries, or authored by Solvay national speakers, though this relationship is omitted from DRUGDEX and often from the studies themselves.

74. Thus, these “OC Spectrum” uses are not only off-label, but also deceptively promoted and scientifically unsupported.

(III) Targeting children

75. Solvay promoted the OC Spectrum theory and depression to pediatricians and pediatric psychiatrists from the moment of launch, though initially there was no approved pediatric use. Then, in 1997, the FDA approved Luvox for the treatment of OCD in children and adolescents. After that approval, Solvay represented to doctors that since Luvox was safe and effective for children and adolescents with OCD, surely it was safe and effective for “OC

Spectrum” diseases common in children, such as ADHD, anorexia, and body dysmorphic disorder.

76. Moreover, Solvay’s sales force actively targeted both pediatricians and pediatric psychiatrists, urging the use of Luvox to treat not only pediatric OCD, but also pediatric depression, anxiety, and depression with accompanying symptoms of anxiety. Those overtures are captured in the call notes recorded by sales representatives following physician calls, as well as in performance evaluations, emails within sales districts, and other materials. Management and representatives recruited speakers to promote these messages as well, through live and recorded promotional and CME lectures of every kind.

77. Any pediatric use for Luvox other than OCD was off-label, but further, it was completely without scientific support. Indeed, even DRUGDEX listed no off-label pediatric uses for Luvox, except Asperger’s Syndrome.

(III) Downplaying side effects and safety issues

78. Solvay portrayed Luvox as a drug with no significant side effect profile. Representatives promised that the drug was superior to other SSRI’s as to sexual side effects and weight gain. In fact, the drug was touted as appropriate for the most fragile populations of patients such as children and the elderly, because of its short half-life, its absence of metabolites, and its supposed “calming effect.”

79. In fact, the drug was particularly ill-suited for such populations. The company was well aware of problems with SSRI drug interactions and the 3A4 pathway that posed cardiological risks, especially in older populations, as described above. Shortly after the FDA approved Luvox, Jack Redmond, Group Product Manager of the Mental Health Marketing Team, and Steve Jennings, Business Director for Cardiology and Mental Health, encouraged sales

representatives to tell doctors that the FDA was not worried about the Cytochrome P450 issue and that if Prozac and other SSRIs were facing indication now, they too would have the same warnings. King's 1999 presentation on selling Luvox to primary care physicians, approved by the company and distributed to the national sales force, was nevertheless typical in cautioning sales representatives not to delve into the problems with SSRI drug interactions and the 3A4 pathway, as described above, unless asked by the doctor. The presentation stated, "The bottom line is, SSRI drug interactions do not kill people. Give your doctors this perspective and don't pursue the topic."

80. Luvox's psychotropic profile, meanwhile, posed special problems for children and adolescents as well. Throughout the years of its promotion, evidence was mounting that taking Luvox and certain other SSRIs increased the risk of mania, including suicidality and homicidal tendencies, particularly in adolescents, as the FDA later cautioned with a black box warning. One such adolescent prescribed Luvox in the midst of this marketing campaign was seventeen-year-old Eric Harris, who, on April 20, 1999, accompanied Dylan Klebold on a killing spree at Columbine High School.

81. The company's response to the public accusations and physicians' concerns that arose after the Columbine killings was to deny the connection between the FDA's admonitions not to trumpet Luvox's safety profile in children and the mounting evidence of adolescents trying to hurt themselves and others while taking the drug, which Solvay continued to downplay. Doctors were told simply that in Harris's case Luvox had not been used appropriately.

82. In promoting Luvox's supposed ideal side effect profile, therefore, the company deliberately omitted and downplayed life-endangering side effects.

ii. Aceon (Perindopril)

a. Regulatory History

83. In December 1993, the FDA approved Aceon (Perindopril) only for the medical indication of “essential hypertension,” or high blood pressure. In May 1999, Solvay acquired the rights from Servier S.A., a French pharmaceutical company, to market Aceon in the United States. When Aceon entered the market, it was the 11th “ACE” inhibitor⁶ to arrive. The market’s response to its launch was a collective sigh of indifference. Until 2005, “essential hypertension” was the drug’s only approved indication. In August of 2005, the FDA approved the drug for treatment of patients with stable coronary artery disease to reduce the risk of cardiovascular death or myocardial infarction. Aceon has not received approval for any other indications.

b. Off-Label Marketing of Aceon

84. Even before the launch of Aceon in October 1999, Solvay promoted Aceon for off-label uses. Off-label promotional schemes used to sell Aceon included the concept of “Arterial Wall Compliance,” the “diabetic kidney” campaign, and the “PROGRESS” prevention-of-secondary-stroke campaign. Each of the schemes is discussed in detail below.

(I) Arterial Wall Compliance

85. As part of Solvay’s 1999 launch of Aceon, Solvay promoted Aceon for Arterial Wall Compliance. Solvay stressed to doctors that Aceon delivered a structural change in all arteries by remodeling them, whereas other hypertension drugs merely lowered blood pressure.

⁶ ACE inhibitors lower blood pressure by inhibiting the activity of angiotensin converting enzyme (“ACE”), which converts angiotensin I to angiotensin II. Angiotensin II causes the muscles surrounding blood to contract, narrowing the blood vessels and increasing the pressure within the vessels. By inhibiting ACE and thereby decreasing the production of angiotensin, the blood vessels dilate and blood pressure is lowered.

In doing so, Solvay pointed to animal research cited on Aceon's label that suggested such a potential effect.

86. Solvay falsely marketed the Arterial Wall Compliance concept even though it knew that the claims were well beyond the bounds of the limited purpose for which the FDA had approved Aceon and lacked any scientific justification, as evidenced by the absence of this use in the drug compendia. The FDA explicitly challenged Solvay on its promotion of unfounded arterial wall compliance effects. In fact, at one point the sales force learned that the FDA was concerned that the claim was unfounded and considering removal of references to arterial compliance from the label. Solvay's training materials confirm that Solvay knew that its Arterial Wall Compliance claim was not only off-label, but without proof. Solvay admitted to its sales force that: "We don't have proof yet. We cannot put an outcome paper in front of them." Yet Arterial Wall Compliance was Solvay's only potential basis for distinguishing itself from other ACE inhibitors. So despite this lack of proof and the FDA's admonitions, Solvay mandated that its representatives push the Arterial Wall Compliance message to doctors ever more vigorously. In addition, representatives throughout the United States paid specialists to deliver Solvay's Arterial Wall Compliance message to primary care doctors, often using Solvay's own materials.

(II) 24-hour Control for the "Diabetic Kidney" and the "Aceon Refinement Message"

87. In the fall of 2000, Solvay began promoting the fiction that Aceon provided "complete 24-hour protection of blood pressure," allowing for the complete protection of a patient's kidneys. Most blood pressure medicines slowly wear off, allowing a rise in blood pressure during the last four to six hours of the dosing interval. This elevated blood pressure is theoretically problematic for a patient's kidney because a substantial increase in blood pressure

could prevent the kidney from properly functioning, in turn allowing protein to spill into the urine. Solvay falsely or with reckless disregard for the truth led doctors to believe that Aceon provided patients with better blood pressure control than competitors throughout the dosing interval because, it claimed, Aceon did not allow a spike in blood pressure during the last 4 to 6 hours of the dosing interval. Accordingly, Aceon allegedly prevented protein from spilling into the urine.

88. Soon after launch, Solvay encouraged sales representatives to focus use of this “24-hour control” story on doctors’ diabetic patients. Diabetes can damage the kidney’s system of filtration, causing protein to pass through the kidney and into the urine. Over time, this damage can lead to kidney failure. Hypertension is a particular concern in diabetic patients because damaged kidneys cannot handle high blood pressure and fail more quickly than healthy kidneys.

89. No scientific support exists for Solvay’s diabetic kidney claims. Although one early study showed that Aceon provided 24-hour protection, other studies have provided conflicting data, demonstrating that Aceon did not provide 24-hour protection as marketed. Moreover, Solvay asked physicians to assume that in the four to six hours before a diabetic patient takes his or her daily ACE inhibitor manufactured by any of Solvay’s competitors, the patient’s blood pressure not only rises, but rises substantially enough to risk the spillage of protein into urine. That leap in logic is dubious at best; the FDA has already determined for each competitor drug that a single daily dose is safe and effective and more frequent dosing is unnecessary.

90. The “diabetic kidney” story and the Arterial Wall Compliance story were two of a handful of sales pitches employed to sell Aceon initially. Despite these promotions, sales were flat after Aceon’s first year on the market. Sales were increasing in John King’s sales territory, however, and he was asked to assist in retooling Aceon’s message in October of 2000.

91. The result was the “Acon Refinement Message.” Solvay embarked on a campaign to increase its Aceon profits by focusing virtually all promotion on the sixteen million Americans nationwide that have diabetes—a highly visible patient population for Solvay’s doctors—and repackaging the deceptive concept of the diabetic kidney. Solvay’s top executives, including Ed Schutter, Solvay’s National Sales Director of Primary Care Sales Force, and John Hepfer, Solvay’s Cardiovascular Marketing Department, and King’s immediate supervisors endorsed this campaign. Solvay adopted the “Acon Refinement Message” as the single sales campaign to be used nationwide to promote Aceon.

92. Solvay’s management demanded that its representatives “aggressively sell[] this message.” Solvay stressed to its representatives that “physicians need to prescribe Aceon for a reason . . . other than you. **This reason is the diabetic kidney.**” Solvay pressured its sales representatives, telling them that the representative still had work to do if the physicians did not state that they prescribe Aceon because of their diabetic kidney patients.

93. Following the national roll-out of the Aceon Refinement Message in January 2001, senior management incorporated the message into a key strategy in the March 2001 Business Plan for Aceon: “Refine current training materials and develop new programs that educate representatives on ACE inhibitors, disease states (diabetes, stroke) and competition.” By June 2001, Solvay had received market research that physicians ranked Aceon first among

hypertensives in effectiveness in diabetic patients and in 24-hour control. In so doing, Solvay intentionally created a brand for Aceon as a diabetic kidney treatment. Once again, patient safety and honesty gave way to Solvay's bottom line.

94. In late 2001 or early 2002, after the Aceon Refinement Message had dramatically boosted sales of Aceon from approximately \$4.5 million in 2000 to over \$21 million in 2001, and King was lauded as a "hero," Solvay added the older off-label promotions, such as the Arterial Wall Compliance campaign, back into the "message."

(III) Stroke Prevention/PROGRESS Trial

95. In the meantime, Solvay had sponsored extensive research in the hopes of proving Aceon's effectiveness in preventing secondary stroke. A comprehensive public relations strategy was in place by October of 2000, including recruiting physicians to attend the June 2001 unveiling in Milan, Italy. But the "PROGRESS" trial results that were issued from Milan were disappointing; they showed that the incidence of secondary strokes in study subjects was lowered, but only once a rarely used diuretic, Indapamide, was added to Aceon. There was no indication that Aceon added any synergistic effect to the diuretic. Plans to potentially file for the required additional indication with the FDA were apparently tabled. Solvay nevertheless trumpeted the results, even in the face of FDA admonitions that such claims were misleading and off-label. It convened an Advisory Board, including CEO Harold Schlevin, to discuss PROGRESS results. Aceon's 2002 Business Plan included comprehensive plans to train speakers on PROGRESS and use the study to improve formulary positioning nationwide. Solvay required its sales force to play audio-CMEs about the PROGRESS trials in doctor's offices and other promotional settings, despite the CMEs' off-label content. In fact, Solvay required its sales

representatives to hold two CMEs per week, or 25 to 50 CMEs per quarter. Its 2002 positioning statement became: "ACEON: The only true 24 hour ACEI to prevent secondary stroke."

96. By November 2001, the impact of the diabetic kidney and secondary stroke campaigns was profound: Aceon had the fastest growing market share out of nine approved ACE inhibitors with 142.6% growth. By July 2002, Aceon had reached 89.71% of its annual sales goal.

97. Solvay's lies likely resulted in inadequate and inappropriate care. Unsuspecting doctors believed Solvay's misleading representations that Aceon was a better hypertension drug than its competitors because it offered complete 24-hour protection of blood pressure, treated the diabetic kidney, helped remodel arteries through Arterial Wall Compliance, and prevented secondary stroke. Consequently, these doctors prescribed Aceon instead of other, often less expensive drugs. But Aceon did not provide extra protection to the diabetic kidney, nor did it prevent secondary stroke or uniquely address Arterial Wall Compliance. If Solvay had not deceived the doctors, these doctors would have prescribed a more appropriate hypertension drug. Thus, patients receiving Aceon based on these misrepresentations were denied appropriate hypertension drugs.

98. While both the diabetic kidney and secondary stroke are listed on DRUGDEX, the listings hardly inspire confidence in the drug. Research cited in support for secondary stroke was the same, unsupportive PROGRESS study that Solvay promoted beginning in 2001. Sometime between 2003 and 2008, DRUGDEX's authors, though listing the same research, downgraded both listings from most supportive category into a middle range, with the strength of the recommendation now only "in some cases." Moreover, the citations include Solvay-

sponsored studies, as well as research or articles of more general import that did not study Aceon at all.

iii. AndroGel (testosterone gel)

a. Regulatory history

99. In 1995, Unimed Pharmaceuticals acquired exclusive rights for Laboratoires Besins Iscovesco S.A. to market AndroGel in the United States. Unimed Pharmaceuticals then sponsored an application for orphan drug designation, which was approved in February 1996, for AndroGel in the treatment of weight loss in AIDS patients with HIV-associated wasting. The FDA has never approved AndroGel to treat weight loss in AIDS patients with HIV-associated wasting. At the same time, Unimed conducted clinical trials for the treatment of testosterone deficiency. In April 1999, Unimed Pharmaceuticals, Inc. submitted a new drug application for AndroGel. Shortly afterward, in July 1999, Solvay acquired Unimed and the rights to AndroGel.

100. In 2000, Solvay obtained FDA approval for AndroGel (testosterone gel) for the medical indication of male hypogonadism. Hypogonadism is a rare condition occurring in men across all age groups associated with a deficiency or absence of endogenous testosterone. The diagnosis of hypogonadism in adult males involves a comprehensive history and physical examination in addition to laboratory test for levels of testosterone and gonadotropins, and possible further testing to determine the cause. The central study featured within AndroGel's label, which is approved by the FDA, employed a normal testosterone range of 298 to 1043 ng/dl (nanograms per deciliter) for the subjects studied; blood levels lower than 298 ng/dl were considered hypogonadal.

101. Primary hypogonadism occurs as a result of congenital or acquired testicular failure. Some common causes of primary hypogonadism include Klinefelter's syndrome (a

genetic abnormality in which a male has two or more X chromosomes in addition to one Y chromosome causing abnormal development of the testicles), anorchia (the absence of testicles at birth), undescended testicles, or an injury to the testicles. Secondary hypogonadism can occur due to a problem with the pituitary gland or hypothalamus. The hypothalamus normally produces gonadotropin-releasing hormone, which signals the pituitary gland to make luteinizing hormone. Luteinizing hormone signals the testes to produce testosterone. Some common conditions that can cause secondary hypogonadism include Kallmann's syndrome (abnormal development of the hypothalamus, which affects the testosterone production cycle) and pituitary tumor that may disrupt the production of the pituitary hormones.

102. In June 2001, Solvay/Unimed joined forces with TAP Pharmaceutical Products, Inc. to co-promote AndroGel in the United States; the agreement ended in 2003.

103. AndroGel is a gel containing synthetic testosterone. The gel is applied to the shoulder, upper arms, and/or the abdomen once daily so that the testosterone can be absorbed through the skin. The product originally came in individual packets. Solvay launched new packaging for AndroGel on September 8, 2004 in the form of a pump.

104. In June 2007, Solvay announced that it submitted a new drug application for AndroGel for treatment of Constitutional Delay in Growth and Puberty in male adolescents ages 13 to 17 years old. As of September 2009, the FDA has not approved this use.

105. In May 2009, after receiving reports of adverse effects in children who were inadvertently exposed to testosterone through contact with a person being treated with testosterone products, the FDA required Solvay and its competitor to include black box warnings on their products, AndroGel and Testim. *See* Press Release, FDA, Testosterone Gel Safety

Concerns Prompt FDA to Require Label Changes, Medication Guide” (August 26, 2009), *available at* <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm149580.htm>. Although the labels for both products warned users to wash hands after application of the product and to cover the treated area with clothing and warned of the potential risk of transfer to female partners, neither label mentioned any risk of transfer to children.

106. Signs and symptoms in the exposed children included inappropriate enlargement of the genitalia, premature development of pubic hair, advanced bone age, increased libido, and aggressive behavior. *Id.* In addition, some of the children had to undergo invasive diagnostic procedures. *Id.* In most cases, these adverse events regressed once the child was no longer exposed to the testosterone products. In a few cases, the adverse effects experienced by the children did not regress; for example, some children’s enlarged genitalia failed to return to age-appropriate size and/or their bone age remained higher than the children’s chronological age.

b. Off-Label Marketing of AndroGel

107. Similar to Luvox, AndroGel was approved for use in a small population of patients—men with hypogonadism. According to many experts, including those cited in a 2002 *New Yorker* article, hypogonadism affects tens of thousands of American men—hardly the basis for a blockbuster drug. Jerome Groopman, *Hormones for Men*, *The New Yorker*, July 29, 2002, at http://www.newyorker.com/archive/2002/07/29/020729fa_fact.

108. Drawing from its experience with Luvox, however, Solvay engaged in a campaign to mass market AndroGel for “andropause,” a supposed condition of male aging, as well as supposedly related ailments such as osteoporosis, sexual dysfunction (as a Viagra substitute), and depression, in male patients with both normal *and* abnormal testosterone levels, with *and* without clinical symptoms. Ever thirsty for expanded sales, over the years Solvay

picked a laundry list of other off-label uses, promoting AndroGel for “wasting” in HIV and AIDS patients, women, methadone and other opioid users, diabetics and those with “metabolic syndrome” (i.e. obese).

109. Some of the off-label uses for AndroGel promoted by Solvay have been listed in DRUGDEX; many have not and thus are not even arguably “medically accepted,” such as andropause, diabetes, metabolic syndrome, and methadone/pain. HIV wasting was actually delisted between 2003 and 2008, apparently because of concerns about the listings. Depression and osteoporosis were downgraded sometime between 2003 and 2008 and fall under DRUGDEX’s middle category, with the strength of recommendation now only “in some cases.” In addition, the studies cited for sexual dysfunction, HIV wasting, depression and osteoporosis were largely sponsored by Solvay, or authored by Solvay national speakers—information omitted from DRUGDEX and in some cases the studies themselves. In fact, the only study cited in support of using AndroGel to treat depression was funded by Solvay and half of the studies cited in support of the sexual dysfunction use and a third of those cited for osteoporosis were funded by Solvay.

110. From the beginning, Solvay’s marketing strategy relied on flawed, even deceptive observations about the likely prevalence of hypogonadism in American men; without these claims, all of Solvay’s marketing schemes would have fallen apart.

111. Solvay launched AndroGel in 2000 touting the unsupported claim that four to five million American men suffered from hypogonadism. For this figure, Solvay cited the FDA’s own website as the source, when in fact the figure came from the manufacturer of Androderm, a testosterone skin patch. By 2004, as AndroGel became Solvay’s bestselling drug, testosterone

treatment had skyrocketed to 2.4 million annual prescriptions—half of the FDA’s supposed prevalence figure and equaling the total number of men aged 40 to 69 in the United States whom the 2004 Massachusetts Male Aging Study (MMAS) estimated were hypogonadal. Solvay responded to the saturation of the market by adopting even more outlandish prevalence figures. In 2005, Solvay began relying on a yet-to-be-published study by Thomas Mulligan, a frequent beneficiary of Solvay funds. Mulligan’s study, Prevalence of Hypogonadism in Males (often referred to as the “HIM study”), which was eventually published in 2006, concluded that a whopping 38.7%, roughly 13.8 million, of American men over 45 seeing their doctors for any reason are hypogonadal, dwarfing the MMAS’s estimated population.

(I) Andropause

112. To create the figures to support the magnitude of silent epidemic that Solvay contended existed, Solvay promoted an expanded definition of hypogonadism. While that promotion began before launch, AndroGel’s sales exploded after the company focused more sharply on such “education.” In 2000, Solvay laid the foundation for sales by convincing influential specialists of an expanded need for testosterone supplementation. An outside consultant reported in 2001 that Solvay had developed its own “consensus guidelines” for testosterone replacement therapy, then brought them to the Endocrine Society with the goal “to have them endorsed” by this supposedly independent group of specialist. Solvay succeeded, thanks to pouring funds into the society and its board members. Over 300 regional urologists and endocrinologists were trained the same year to speak on the “importance of TRT [testosterone replacement therapy] and the critical role of Andropause.”

113. In late 2001, Solvay was ready to more fully capitalize on its educational efforts. It directed its sales force that the goal for 2002 was “to grow the market. . . . Instead of going

after a bigger piece of the pie, we need to make a bigger pie.” Primary care was targeted as the main source for such growth. Representatives were instructed to avoid the term hypogonadism with such doctors and use the friendlier phrase “low T” instead. “Peer influence” efforts were redoubled in 2002 to assist in the primary care sector. Sales from 2001 had been \$115.8 million; by November of 2002, annual sales had already reached \$164 million.

114. The “education” Solvay provided to physician customers and speakers concerned the supposed existence of andropause and widespread need for hormone replacement therapy in men. Solvay noted the overall decline in testosterone among men as they reach old age, but claimed that such a decline was not a “normal” part of aging but a disorder affecting strength, well-being, cognitive function, and sexual function, and other attributes, sometimes disproportionately or acutely, not unlike menopause. Solvay called testosterone replacement therapy “HRT”—“*his* replacement therapy,” an allusion to hormone replacement therapy for women.

115. Importantly, in identifying those supposedly suffering from andropause, Solvay applied the same normal range for testosterone to octogenarians that it did to twenty-year-olds. Then it applied a substantially overinclusive screening tool to identify men possibly suffering from hypogonadism. The Androgen Deficiency in Aging Males (“ADAM”) questionnaire, still in use today, asks questions that would make virtually every aging man a candidate for AndroGel, such as:

- Do you have a decrease in sex drive?
- Do you have a lack of energy?
- Are you sad and/or grumpy?
- Are you falling asleep after (during) dinner?

116. As the long title of the questionnaire indicates, however, the questionnaire was never designed to identify male hypogonadism. It was designed instead to identify “androgen deficiency in aging men,” in other words, andropause or “age-associated” hypogonadism, a hypothesized condition not within AndroGel’s label, not listed in any drug compendium and for which no drug has been FDA-approved to treat. Moreover, the author of the study out of which the questionnaire arose, and his institution, St. Louis University, were beneficiaries of Solvay’s largesse and partners in promoting the drug for years afterwards through a roundtable series, CMEs, and other programs.

117. Andropause is not a widely-medically recognized disease and remains the source of great controversy and debate. It has never been listed in any drug compendium. The notion that sex hormones maintain or improve a person’s health into old age has turned out to be a flawed one as applied to women, most famously with regard to the World Health Organization’s estrogen replacement study, which was aborted because of the prevalence of dangerous adverse effects. The facile way in which Solvay urged and continues to urge the same theory for aging men may endanger men’s health in similar ways. In particular, steroid and testosterone use are associated with prostate cancer. Moreover, the FDA has long made clear that andropause falls outside of the drug’s approved indication and labeling.

118. Coaxing physicians into screening patients through the ADAM questionnaire was crucial to Solvay’s marketing plan, because positive results were frequent, and led either directly to an AndroGel prescription, or to a testosterone test. Indeed, testing strategies were also central to the marketing of AndroGel, as Solvay exploited the notorious unreliability of such tests in hopes of false positives. With older men, Solvay suggested, a free testosterone test was superior

to a total testosterone test, the standard test, and further, if a total testosterone test came back in the low-normal range or the borderline hypogonadal range, a free testosterone test should be performed as well. Doing so, Solvay and its speakers claimed, would “reveal” that the true population of American hypogonadal men was not 13.8 million, as the HIM study concluded, but an incredible 20 million men.

119. Relying on these strategies of heavy “screening and testing” allowed Solvay to cast an extremely wide net in fishing for patients; it also segued easily into the promotion of AndroGel to aging men with normal testosterone levels and men with “age-associated” hypogonadism, despite the FDA’s warnings.

120. Sales training materials circulated and adopted in the Mid-Atlantic and Southwest districts, for instance, reflecting marketing strategy nationwide, proposed in July 2001 that testosterone supplementation was necessary for the well-being of many aging men with normal testosterone levels. Perhaps, the materials posited, a man in his fifties was accustomed to a testosterone level of 1000, but experienced a sudden drop in testosterone that nevertheless remained in the normal range. Training materials urged that to *feel* “normal,” that man needed to boost his testosterone levels. Representatives were told to ask doctors to look at how far a man was *from the top of the normal range*, rather than how far he was *from the bottom of the range*. As long as AndroGel treatment would not boost a patient’s testosterone levels above the normal range, he was a candidate.

121. By 2004, as AndroGel’s pump launched, district managers spoke and wrote openly to their supervisors and their sales representatives about “find[ing] ways to change doctors’ perception about what’s a ‘Normal’ T level.” For support, the sales force was told to

rely in part on specialist speakers. Some speakers attended centralized training sessions; they returned to their districts encouraged to prescribe AndroGel to patients within normal levels who seemed be suffer from malaise or other symptoms. Other speakers spoke within their districts after attending other speakers' events. All speakers were provided suggested slides, but encouraged to voice their own opinions. Messages not on Solvay's script, including off-label messages, were not required to be reported or approved. Speakers like San Antonio-based Dr. Ramon Perez first catapulted to nationwide speaker status in 2003 by pressing the envelope regarding "normal" testosterone levels.

122. For additional support in challenging definitions of hypogonadism, representatives were instructed verbally and in writing when detailing doctors to rely on the American Academy of Clinical Endocrinologists' ("AACE") 2002 consensus guidelines. These guidelines mention but do not endorse some specialists' application of an algorithm to determine what the testosterone level threshold should be for treating men suffering from hypogonadism caused by "aging." The guidelines were circulated to the sales force with an unheeded cover letter warning representatives not to use them for promotion.

(II) Andropause-related off-label uses: depression, osteoporosis, and sexual dysfunction/Viagra substitute

123. A favorite angle for selling AndroGel has often been to urge the treatment of symptoms. Representatives encouraged primary care physicians presented with middle-aged men complaining of depression to consider low *or decreased* testosterone levels as a cause and to prescribe AndroGel to treat the depression, with or without prior blood tests. Solvay convinced doctors that men with hypogonadism or decreased testosterone levels frequently suffered from depression-like symptoms; thus, if AndroGel helped the patient's depression, low

testosterone would be shown to be the underlying cause. Solvay admitted to its pharmaceutical representatives that the studies upon which it relied did not include men in the normal testosterone range. Despite the lack of scientific evidence, Solvay advanced these patently false and potentially dangerous claims.

124. Depressed men with normal testosterone levels who received AndroGel were deprived of medically effective and legitimate drugs that could treat their depression. Instead of noticing improvement from AndroGel, these men were likely forced to return to the doctor for additional visits so that their depression could be treated with drugs that actually worked. Perhaps more dangerously, depression can be linked to dangerous conditions such as cardiovascular disorders; treating the symptom in lieu of investigating underlying causes risked patients' health.

125. Solvay also promoted AndroGel as a treatment for the off-label indications of osteoporosis or risk of osteoporosis in elderly men with potentially low *or decreased* testosterone levels. Solvay representatives and speakers pointed to data cited in AndroGel's label that suggested that supplementing testosterone in truly hypogonadal men was linked with increased bone density. But even in studies that have found a positive correlation between testosterone levels and bone strength, the hormone accounted for only about five per cent of age- and weight-adjusted differences. Moreover, men with severely low testosterone levels showed improvement in the spine, but no change was observed in the hips, and these are the fractures that most commonly debilitate those with osteoporosis. Exposing elderly men to testosterone that increased risks of prostate cancer and other disorders in exchange for this potential benefit to bone health was not only an off-label effort, but controversial at best for those without severe

testosterone deficiency.

126. Solvay also promoted the off-label use of AndroGel as a substitute for Viagra in the treatment of sexual or erectile dysfunction, although there was limited or poor documentation demonstrating that AndroGel was effective in treating erectile dysfunction. Viagra was considered a competitor drug in this sector, and Solvay coached sales representatives to ask doctors to substitute AndroGel for Viagra, particularly when patients continued to complain of dysfunction after treatment with Viagra. Again, this marketing scheme placed patients at risk because patients did not receive effective treatment to determine the underlying cause of the sexual dysfunction, such as cardiovascular disease, which is much more highly associated with erectile dysfunction than is hypogonadism. Hypogonadal levels of testosterone are in fact associated with decreased libido, and not with erectile dysfunction, in all but the rarest and most severe of cases. Solvay was and is happy to blur the lines between these distinct medical problems, and continues today to promote AndroGel as a treatment for erectile dysfunction.

(III) Use in women

127. Solvay also promoted AndroGel for use in women despite specific warnings on the drug's label that women must not use it. Solvay sales representatives actively pursued obstetricians and gynecologists, who were placed by senior managers on representatives' target lists. Estratest, an older Solvay drug, non-FDA-approved and containing both estrogen and testosterone, proved handy for marketing to these doctors. Solvay representatives had already convinced numerous endocrinologists of the merits of Estratest and testosterone supplementation for increasing libido and well-being in women. The approach pitched to physicians was to treat

symptoms; testing women's testosterone was not discussed or performed. It was simple to transition from Estratest to AndroGel with such physicians, now accustomed to supplementing testosterone without prior testing; they were already "sold" on the benefits for women (and easily coaxed to explore treating with men as well).

128. The company reworked an old non-branded brochure for women created to help drive demand for Estratest, adapting it to AndroGel. The brochure was used by the Solvay sales force nationwide; Tom Dovel, for example, a district manager in the mid-Atlantic region, directed his sales representatives to use the brochure to detail physicians regarding the use of AndroGel in women.

129. Women normally produce testosterone in levels significantly lower than in men, and maintaining those levels is associated with libido in women, just as in men. But while testosterone supplements are sometimes recommended for women unable to produce testosterone, after full hysterectomy, for example, Solvay has never sought or obtained such an indication for AndroGel. Further, marketing AndroGel for women put such patients at risk, because testosterone therapy in women generally requires smaller doses than the AndroGel packaging allowed to be metered out, and the drug's labeling did not reflect full associated risks or directions for use. In particular, AndroGel was first packaged in small single-use packets. Sales representatives encouraged physicians to prescribe AndroGel to women and direct them to use a rough quarter of the pack at a time. The imprecise nature of the dosing was justified to physicians as a downside worth enduring because "anything's better than nothing" for women in need of testosterone supplementation.

130. Excessive testosterone in women produces serious adverse effects, such as acne, body hair growth, scalp hair loss, and a decrease in high-density lipoprotein (HDL) cholesterol levels, increasing the risk of heart disease. The balance between sufficient and excessive testosterone in women is a delicate one. An uncertain number of women likely suffered such adverse affects as a direct result of Solvay's marketing tactics.

(IV) Laundry list of off-label promotions related to other target patient populations for AndroGel, including diabetes, HIV/AIDS

131. Recognizing that screening and testing of virtually any male population for "low testosterone" would lead to AndroGel scripts because of the overinclusiveness of the ADAM questionnaire and the unreliable nature of testosterone testing, Solvay has consistently aimed to expand the testosterone supplement market through identifying patient profiles with potentially higher incidences of hypogonadism and encouraging doctors to "screen, test and treat" these candidate patients. Solvay began by pursuing men over 45 years of age, HIV and AIDS patients, erectile dysfunction patients, and patients feeling fatigued or depressed as candidate patients that may be hypogonadal. By 2002, Solvay had incorporated a plethora of chronic illnesses, such as diabetes, abdominal obesity (sometimes referred to as "metabolic syndrome" or "MS"), chronic renal failure, rheumatoid arthritis, coronary atherosclerosis, and chronic liver disease, into its lists of target patient populations. In short, AndroGel had as many potential uses as snake oil.

132. Solvay's approved AndroGel print ads cited to the HIM study and stated, for instance, that diabetic men were twice as likely to have low T. In the field, however, marketing became more direct: representatives spoke about the difficulty of treating non-compliant, overweight diabetic men and suggested that AndroGel could help manage, or even improve, patients' diabetes. Representatives claimed that AndroGel could increase such men's lean

muscle, decrease their fat, get them moving off the couch, and, pointing in part to data on AndroGel's label that suggests that insulin therapy for diabetics may be affected by testosterone levels, potentially eliminate the need for some diabetes medications. It was Solvay's upper management that directed AndroGel to be marketed for the treatment of diabetes, but training was indirect and discreet. District managers gathered at national meetings for instruction in the sophisticated science related to diabetes necessary for making the pitch, which was delivered by trainers or opinion leaders. District managers then returned to their respective districts to train their own representatives.

133. Similarly, in the obese, it was claimed that AndroGel could reduce fat and increase lean body mass. Not only do men on long-term opioids experience a reduction in testosterone, representatives asserted, but increasing testosterone could potentially supplement pain management, representatives suggested to physicians.

134. Solvay has spent considerable resources marketing AndroGel to the HIV/AIDS patient population. In fact, Solvay created an AndroGel Specialty Sales Force that focused on marketing AndroGel to AIDS treatment centers. Although orphan drug designation had been obtained for AndroGel in the treatment of weight loss in AIDS patients with HIV-associated wasting, the FDA never approved AndroGel for this indication, thus barring Solvay from promoting this off-label use. But knowing that the FDA had approved AndroGel only for the treatment of hypogonadism, in 2000, Solvay nevertheless promoted AndroGel to treat AIDS wasting caused by a combination of food malabsorption, loss of appetite, and increased metabolism. Doctors often prescribe steroids to HIV or AIDS patients with wasting to help replenish their lean muscle mass and body weight and improve physical endurance. Solvay used

AndroGel's qualification as a steroid as the sole basis for marketing AndroGel as a treatment for wasting, lethargy and fatigue.

135. Solvay's sales aides targeting this population consistently misstated clinical research and misled doctors about the prevalence of hypogonadism in those with HIV or AIDS in order to support routine screening and testing. The aides cited figures as high as 50% in the HIV population at large, even though the data supported only about a 38% prevalence, and then only in the days preceding anti-retroviral therapy, when AIDS was widespread, with nearly all hypogonadal test results found among those with full-blown AIDS. Many HIV clinics began routine testosterone testing as a result, often setting a somewhat high 350 ng/dl as the lowest normal level, while others employed the ADAM questionnaire as a screening tool first, despite research that shows its failure to detect hypogonadal patients in this population. As a result of these deceptive practices, AndroGel's use flourished, particularly among Medicaid patients in HIV practices.

136. Probably related to Solvay's increased targeting of these laundry list patient populations over the years is Solvay's apparent increased difficulty in keeping patients on testosterone therapy long-term. While true hypogonadism in many men, including Klinefelter's syndrome sufferers, is a permanent condition, Solvay's patients typically used AndroGel only for limited periods of time, often for periods shorter than physicians' recommended treatment course.

B. Solvay's Delivery of the Off-Label Messages about Luvox, Aceon and AndroGel

137. Solvay disseminated its off-label messages about Luvox, Aceon and AndroGel through several means. At the highest levels, Solvay reached doctors and shaped opinions about

its drugs by supporting research related to the drugs through large unrestricted educational grants. Where research fell short, Solvay sought out supposedly independent associations of specialists to issue “clinical practice guidelines” or “consensus guidelines” in favor of controversial positions that impacted its drug sales. In the first years of AndroGel’s launch, for instance, Solvay sponsored the Endocrine Society and other such associations through grants, and by ensuring that its board was peopled largely by physicians receiving Solvay funds.

138. Upon information and belief, Solvay also purposefully manipulated drug compendia, such as DRUGDEX, and caused them in some cases to list desired off-label uses despite shoddy evidence that did not actually substantiate or fortify the uses. For example, Solvay sponsored research on the use of Aceon in treating secondary stroke in patients, but the PROGRESS trials failed to demonstrate that use of Aceon alone could lower the incidence of secondary strokes in the study subjects, as Solvay well knew. Despite this negative result, this Solvay-sponsored study appeared in DRUGDEX.

139. Moreover, upon information and belief, Solvay misled drug compendia about its financial sponsorship of studies it submitted, and about its relationship with authors of studies it submitted. For example, the 2003 edition of DRUGDEX listed a study on the use of Luvox to treat panic disorder that was supported by a grant from Reid-Rowell Pharmaceuticals, Inc. Solvay wholly owns the pharmaceutical company, but that relationship does not appear in the article. DRUGDEX also listed a study on the use of AndroGel to treat depression in men with low or borderline testosterone levels conducted by H.G. Pope; a review of the published study demonstrates that the study was supported in part by a grant from Unimed Pharmaceuticals, later acquired by Solvay. The 2003 edition of DRUGDEX listed a study on the use of AndroGel to

treat sexual dysfunction in men authored by Adrian S. Dobs and A. Wayne Meikle, both AndroGel speakers for Solvay. DRUGDEX also listed a study on the use of Luvox to treat panic disorder conducted by Dr. Joseph Zohar, a frequent beneficiary of financial support by Solvay and a Solvay speaker on Luvox. Yet DRUGDEX's listings make no mention of these studies' financial relationships to Solvay, and, upon information and belief, Solvay concealed those connections in some or all instances.

140. Solvay's sales representatives also conveyed off-label messages directly to physicians nationwide in order to persuade them to prescribe the drug. Solvay's sales force is divided into various specialty groups, including primary care. Primary care sales representatives are typically responsible for marketing several drugs at the same time, and from 2000 to at least 2002 representatives in this sector marketed all three drugs at the center of these allegations. Solvay required its sales representatives to make frequent calls on doctors targeted by management—using detailed prescribing data available commercially—as high prescribers or potential high prescribers. The goal was to identify high prescribers within a product's drug class and high potential prescribers of the drug in addition to those already heavily prescribing the drug. High Medicaid prescribers were often included in such lists. For example, a 2001 Atlanta District Business Plan encouraged sales representatives to “Focus on cash pay and Medicaid patients . . . Utilize Medicaid stickers where appropriate.”

141. Solvay also actively targeted doctors who were members of states' Medicaid pharmaceutical and therapeutic (“P&T”) committees and pushed its off-label messages for its drugs in an effort to obtain placement of its drugs on the state Medicaid formularies. Nationwide, representatives and managers devoted great effort to learning what physicians

served on P&T committees. Representatives sometimes offered preceptorships (i.e. cash) to physicians willing to disclose such members. Once a board member's identity was discovered, the sales force showered the member with offers of gifts, dinners, and every kind of bribe in exchange for hearing Solvay's off-label details. Such members often had no clinical practice, or specialized in a different area of medicine; they too received such treatment. Nor was entertaining board members limited to launch periods for the three drugs; it was ongoing for fear that a favorable position on a preferred drug list would be lost or in the hope that an inferior position would be reversed. Wooing P&T committee members was discussed openly and earnestly on periodic conference calls with upper management. On one such call, Ed Schutter, Solvay's National Sales Director of Primary Care Sales Force, offered to meet in person with a committee member who was falling under Solvay's influence. On another, management brainstormed about coaxing a committee member to have dinner by offering her a babysitter for her children. Once at dinner, or whatever event was chosen, committee members heard the same off-label messages that other physicians received from Solvay representatives.

142. Mike Bullington, Regional Business Director for the Central Region, covering Alabama, Mississippi, Florida, Louisiana, Arkansas, Tennessee, and parts of Texas, encouraged his sales team members to "wine and dine" these doctors, even doctors who never prescribed Solvay drugs or were retired. His district provides an example of Solvay's efforts to influence P&T committees. In a March 2002 e-mail, Jean Anderson, a Solvay sales representative based in Montgomery, Alabama, reported to Drew Manning, her district manager, that she had discussed Aceon and the PROGRESS study with Dr. Tim Covington, Chairman of the P&T Board for Alabama Medicaid, and had learned that Dr. Covington favored Aceon for stroke patients

because of the PROGRESS study. Manning in turn forwarded this information to the Birmingham sales team and advised them to initiate discussions with doctors who were “big Medicaid writers” to determine if any of these doctors were influential with the Pharmaceutical and Therapeutic committee or any other Medicaid affiliate and solicit their support for Aceon as the drug of choice for Alabama Medicaid stroke patients.

143. CMEs were another frequently-used medium for off-label messages. Solvay sponsored and improperly influenced live CMEs relating to off-label topics, often given in conjunction with lunch or dinner. Solvay representatives would often provide doctors an opportunity for CME credit during calls by playing a pre-recorded CME, typically on an off-label topic, often influenced by Solvay with regard to content and speaker choice, while the representative provided a free meal to the doctor and the doctor’s staff. Representatives commonly handled the application for CME credit on behalf of their doctors, even filling out required quizzes on the contents of the CME. Sometimes the CME was delivered on leave-behind CD-ROM’s, such as the PROGRESS study CD-ROM, touting the benefits of Aceon to prevent secondary stroke. Sometimes CMEs were delivered by means of an audio conference over the telephone. Solvay referred to this method as Instant Recall Audiotex (IRA) or “distance learning.” Solvay often required its sales representatives to meet quotas regarding these in-office CMEs. For example, district managers required Solvay sales representatives to conduct at least two PROGRESS CD-ROMs per week.

144. Solvay conveyed off-label messages through promotional speakers as well. Solvay’s promotional speakers ranged from “coachable” country doctors recruited by sales representatives to thought-and-opinion leaders speaking on a national circuit. Solvay

representatives and district managers often hired local specialists to speak to primary care physicians, such as urologists to tout the benefits of AndroGel, cardiologists to praise Aceon, and psychiatrists to recommend Luvox. Particularly effective speakers sometimes traveled throughout a territory with a representative on a circuit of different speaking engagements. Typically, handouts and a meal were included. Solvay exerted little oversight over its speaker program and few uniform procedures existed. Some speakers received training on speaking or education on off-label subject matter, while others received none. Some used company-prepared slides; some created their own. Regional speakers' fees were negotiated in a piecemeal way in each district.

C. Solvay's Widespread Use of Kickbacks

145. As a small company trying to gain market share in an increasingly competitive industry, Solvay lacked the clout to cut deals with prescription benefit management services and major health systems. Solvay compensated for its size by engaging in particularly aggressive physician marketing efforts.

146. Solvay bribed doctors to use its drugs. Whether the kickbacks took the form of bogus speaker programs, honoraria, Dine-N-Dashes, Lunch-N-Learns, cash payments or other similar schemes, the motive was the same—to lock in patient referrals (i.e. prescriptions). The recipients of these attentions were, as always, the high actual or potential prescribers on representative's target lists. For instance, district managers set aside money to send two to three “high potential HIV writer[s] of testosterone [AndroGel] to a weekend program at a desirable location.”

147. In addition to tainting those prescriptions that arose out of these schemes, Solvay's kickback strategy raised the total cost assumed by Medicaid because doctors, blinded

by Solvay's remunerations, prescribed: (a) Solvay drugs that they would not have if not for the kickbacks; (b) medically unnecessary and ineffective drugs; or (c) more expensive Solvay drugs for which Medicaid ultimately paid.

148. Because Solvay's kickback schemes are intertwined with its off-label promotion of Luvox, Aceon and AndroGel, capturing off-label prescriptions for Luvox, Aceon and AndroGel captures not only the cost to Medicaid of Solvay's off-label marketing but also profits tainted by kickbacks.

i. Cash-for-Prescriptions Schemes

149. Solvay executives, managers, and sales representatives cooked up several kickback schemes in order to provide "incentives" in the form of cash to these high-prescribing physicians and to induce other physicians to prescribe high volumes of Solvay's drugs. Many of the schemes are variations on the same theme: pay doctors to fill out minimal paperwork on patients taking Solvay drugs, supposedly to further medical knowledge. While the cash paid to physicians under these schemes generally took the form of "honoraria" or "consulting fees," the sheer number of these schemes, their similarity, sales representatives' high level of discretion with their budgets, and the sparseness of the obligations imposed on physicians in exchange for the cash, point to the conclusion that these "programs" were mere incentives/rewards for prescribing Solvay drugs.

a. Speaker Programs

150. Solvay's speaker program was a poorly disguised kickback. Solvay hired selected doctors to give talks in promotional settings about Solvay's drugs and their off-label uses. Internal documents attest that Solvay sought "coachable" doctors willing to laud Solvay drugs' effectiveness to other doctors. Some speakers were chosen as a reward for prescribing drugs.

Solvay trained these speakers through either a single conversation with a sales representative or at regional training sessions. Speakers learned Solvay's off-label "message," and presented remarks scripted by Solvay sales representatives, using materials created by Solvay sales representatives. These programs often lacked scientific, medical or educational value because they were largely used as vehicles for promoting off-label messages that were themselves misleading and unfounded.

151. Speakers often attended Physician Speaker Facilitator Workshops ("PSFW") or Speaker Training Meetings for which Solvay allocated \$130,000 per program. An attachment to an October 8, 2001 e-mail from Shaji "Shawn" Durrani, Regional Marketing Manager-Cardiovascular for the South Central region, to the MTA-Field PC DM, Ed Maker and Michael Bullington contained the following description of these meetings:

PSFW: A PSFW is a Speaker Training Meeting, identical to the ones which occurred in 2001. The cost of a typical program is \$130,000, but cost may vary depending on your specifications. These meetings must fall in line with AMA guidelines and content is pre-determined by the home office. We recommend at least one of these per region in 2002. More than a few per region could be suspect, as one only needs so many speakers.

152. In addition, speakers were offered honoraria for their speaking engagements. The amount of speakers' honoraria varied and was negotiated on an individual basis by sales representatives. Solvay's payments to these doctors greatly exceeded the fair market value and reasonable compensation ordinarily given to a speaker in a typical arms-length transaction, particularly as presentations were often short and the audiences small. For example, in May 2000, Solvay paid one doctor, Dr. M.B., \$10,500 in one month to speak to fewer than 50 people about Aceon, and over \$100,000 for speaking engagements in 2000. Another doctor, Dr. R.A. conducted three Aceon speaker programs, costing a total of \$5,314, on March 5 and 7, 2002.

\$1,000 was a typical price for a quick presentation. Speakers were encouraged to speak at back-to-back events as often as several times a week, and no audience was considered too small.

153. Further, Solvay frequently held speaker programs at upscale venues and invited and paid for the speaker's family to attend as well. Solvay's management encouraged representatives to select creative venues for speaker programs such as holding them at sporting events and dinner cruises. For example, in 2000, Solvay hosted a speaker program on Aceon at Beau Rivage, an upscale resort and casino in Biloxi, Mississippi. Solvay held other programs at gourmet wine galleys. Solvay's venues and excessive compensation reveal that the focus of these speaker programs was on wining and dining doctors rather than on exchanging scientific and medical information.

154. In addition to the money Solvay gave the doctors directly, speaking engagements were a rich source of referrals and Solvay allowed speakers to invite promising referral doctors to their speeches. In addition, Solvay sometimes paid doctors to attend such speaker events in the form of \$100 gift certificates. Thus, Solvay's speaker programs provided doctors with a networking benefit for the purpose of increasing the speaking doctor's own business, a kickback within a kickback for the speaker, plus attendees often received their own kickbacks.

b. Preceptorships

155. Another Solvay kickback scheme involved preceptorships. "Preceptorship" describes an arrangement where a doctor allows a pharmaceutical representative to shadow him for part of a day (usually four to eight hours). During this time, the representative promotes and sells Solvay products to a captive audience. Solvay used preceptorships to market its off-label uses to doctors. Indeed, Solvay mandated that its representatives participate in at least four preceptorships per month. In exchange for allowing the representative to shadow them, Solvay

paid the doctors anywhere from \$150 to \$1,000. From January to June 2001, Solvay sales representative Tonya Stringer participated in five preceptorships. Similarly, the Atlanta Business Plan for January through June 2001 prepared by Dan Gobat set aside \$4,500 from the Aceon budget for 18 preceptorships.

c. Honoraria and Grants for Bogus Clinical Trials, Studies and Focus Panels

156. Solvay paid doctors honoraria and grants for bogus clinical trials and studies, focus panels, and other similar schemes in exchange for prescriptions.

(I) Marketing Feedback Panels – Luvox, Aceon and AndroGel

157. Marketing feedback panels, or focus panels, were one of Solvay's earliest and most abusive kickback schemes, which it employed in promoting all three drugs. When Luvox was first launched in 1995, Solvay was a substantially smaller company with about 300 sales representatives. Sales representatives would invite doctors from across the country to fly to a luxury hotel or resort and listen to speakers promote Solvay's new drugs. Solvay not only paid for each doctor's airfare and lodging, but paid each doctor an attendance fee to attend the speaker's program. To attempt to legitimize this scheme, Solvay representatives called the doctors "consultants," and asked them to comment afterwards on the effectiveness of Solvay's sales pitches. A typical destination for such luxury weekends was Hiltonhead Island in South Carolina. In one instance, Solvay sales representatives hosted an estimated \$2,300 focus panel on March 18, 2000 at Grandover Golf Course in Greensboro, North Carolina, rated one of "America's Best Places to Play" in Golf Digest. Solvay also heavily relied on these feedback panels to promote Aceon when it was launched in 1999.

(II) District or Regional Advisory Boards

158. Solvay also used district or regional advisory boards as a way to funnel kickbacks to physicians. Solvay would gather local physicians for purposes of providing Solvay with feedback on how to market its drugs. These district or regional advisory boards were open venues where off-label indications of Solvay's drugs would be discussed. In exchange for participating in these events, the physicians would receive a fee or honoraria.

159. In an October 8, 2001 e-mail from Shaji "Shawn" Durrani, Regional Marketing Manager-Cardiovascular for the South Central region, to the MTA-Field PC DM, Ed Maker and Michael Bullington, Durrani sent the proposed AndroGel 2002 Budget for the South Central region, which allocated \$30,000 for regional advisory programs. An attachment to the e-mail gave the following description of regional advisory programs:

Regional Advisory Panel: Physicians attending a Regional Advisory Panel are paid consultants. Too many of these programs could be suspect, as one only needs so many physician advisors. These programs will likely be conducted with the help of your Medical Liaisons. We recommend 0 to 4 per region, but you may do as many as you please.

160. Another Advisory presentation consisted of a discussion by a public relations firm on promoting AndroGel for sexual dysfunction since states' approval of sexual dysfunction may allow doctors "an opportunity to reach out to reporters and ensure they understand testosterone's role in sexual dysfunction and on libido."

(III) ALERT Testing & Screening Program - AndroGel

161. Solvay and Unimed, a Solvay company, instituted this AndroGel screening program sometime before 1999. It continued until sometime in or before 2002. It originally involved a one-day screening event plus patient follow-up. The program was later extended beyond the one-day screening events, and representatives began to pay doctors in the form of

“speaker’s honoraria;” doctors continued to log new patients on Solvay screening forms, and representatives periodically collected the logs. Participating physicians, both specialists and primary care doctors, signed written agreements promising to advertise the screening event and to identify those among their patients who might suffer from hypogonadism. The physician agreements mention testosterone blood test levels, but explicitly state that blood tests are discretionary.

162. Under the ALERT contract, physicians were to be paid \$500 upon “completion” of the program. For example, from January to June of 2001, Sales Representative D. Pallone placed ALERT kits with four different doctors, who screened an average of 16 patients per doctor for a total of 63 patients. The four doctors had been paid a total of \$1500 in “honoraria,” with more funds requested as of the date of the report.

163. In addition, participating doctors and nurses were given pre-paid calling cards containing up to 20 minutes of free calls per patient, for up to 40 patients. Ten minutes could be earned per patient by reporting patients’ symptoms, ADAM questionnaire results and giving a blood test. Ten additional minutes could be earned by reporting blood test results and any drug prescribed. Finally, Solvay also provided funds for doctors to advertise their screening events, and to cover the expense of adding the ADAM questionnaire to patient history forms.

164. Physicians were told that Solvay would collate the content of the logs for a study, but the study never appeared.

(IV) CME Case X-change

165. Shortly after Aceon’s late 1999 launch, Solvay created the “CME Case Exchange” program as part of its off-label campaign to promote Aceon as preventing secondary strokes. Physicians chosen for their high number of Aceon prescriptions were invited to a CME

event organized and controlled by Solvay at which a speaker would deliver the “Aceon message.”

166. Initially, doctors were asked to appear at a kickoff event with a form filled out, describing a case study appropriate for Aceon’s message for secondary stroke patients, and answering questions regarding whether Aceon was prescribed. In Dallas, one such event was given at a skybox at a football game. In exchange, they were entitled to \$150 “honoraria” for every case study form submitted to Solvay. Solvay’s stated purpose was for an editorial board to collect the case studies and periodically circulate a newsletter to participating doctors featuring particular cases to educate doctors about secondary stroke. No newsletter was ever written or circulated, and no use was ever made out of the information.

167. Solvay used the same strategy in promoting off-label uses for AndroGel, creating case exchange programs for AndroGel. An attachment to an October 8, 2001 e-mail from Shaji “Shawn” Durrani, Regional Marketing Manager-Cardiovascular for the South Central region, to the MTA-Field PC DM, Ed Maker and Michael Bullington, described the AndroGel case exchange program as follows:

Case Exchange: Case exchange programs are under development at this time, but will involve physician interaction and presentation of case studies. These programs will be similar to those conducted with ACEON in 2001. Our cost estimate for one of these programs is \$4,500, but could vary. You may conduct as many or as few of these programs as you please.”

(V) ACES Consultation Program – Aceon

168. Beginning in late 1999, Solvay entered agreements with doctors, initially from the Texas area, under which doctors would act as “consultants” on Aceon use. Physicians were expected to “record blood pressure changes on a very modest number of Aceon treated patients over two follow-up visits,” which information Solvay would compile according to race, age and

sex and distribute to participants. In exchange, Solvay would pay each “consultant” \$100 per patient trial.

(VI) Aceon Community Trial (“ACT”) & REACT

169. Upon launch of Aceon in 1999, Solvay recruited and paid doctors to participate in what was billed as the Aceon Community Trial, to be published as a phase-four trial. The program commenced with nationwide orientation sessions for targeted doctors at luxury hotels. The physicians were paid to attend the sessions. In addition, they were paid an initial payment followed by a second payment following enrollment for participating in the trial. Materials advertised ACT as “an open-label, community-based investigation of how well ACEON tablets controls (sic) blood pressure in various groups broken down by such variables as gender, age, and race.” Solvay set a goal of enrolling 2,000 physicians to enroll 10,000 patients, and to that end solicited 9,000 physicians.

170. After the orientation sessions, physicians were required to turn in to Solvay various paperwork, including a signed agreement, a C.V., an IRS W-9 form (for payment), and a confidentiality agreement. Patients were put on Aceon and tracked for purposes of the study. Solvay repeated the promotion with “REACT,” targeting 1,000 physicians who had never prescribed Aceon. Participants received free samples and “medical education.”

171. Solvay apparently did publish a study in some form. Nevertheless, Solvay saw ACT and REACT as essentially physician-enrollment programs.

(VII) Aceon Physician Profile Interviews

172. Before Aceon was launched, representatives were asked to meet with doctors who prescribed high volumes of hypertension drugs. The 30-minute interviews had the stated purpose of learning about the physician’s practice and treatment of hypertension. In exchange

for the interview, the physicians signed “Expert Interview Consultant’s Fee Request Forms.” The representatives delivered \$100 checks after launch of the drug, providing an opportunity to give these coveted doctors the full Aceon sales pitch.

(VIII) Solvay Interactive Representative Training Program (CITY)

173. In 1999, Solvay invited physicians to sign consultancy agreements under which physicians promised to listen to Solvay sales pitches for Aceon and provide feedback regarding their content and impact for up to two hours, in exchange for cash. At an initial dinner, participating physicians filled out questionnaires gauging reactions to sales representatives’ off-label promotional campaigns, including “Arterial Wall Compliance” and “the diabetic kidney.” In exchange, as their contracts specified, they were entitled to \$250. The physicians were not paid at the dinner, however. Instead, representatives told the physicians to go back to their practices and “get experience” with Aceon to allow them to serve better as consultants—i.e., prescribe Aceon. The representatives would “catch up” with each physician later, and pay not only the \$250, but also an additional \$100 for every patient newly prescribed Aceon.

(IX) Continuing Medical Education Seminars (CMEs)

174. Solvay also paid doctors for prescribing Solvay drugs by reimbursing them for their CME expenses. The AMA standards, adopted by Solvay, forbade Solvay from directly or indirectly paying a doctor to attend a CME. Likewise, the standards prohibit Solvay from directly paying a doctor for presenting at a CME; rather Solvay must pay the CME provider (who will in turn reimburse the doctor). Disregarding these guidelines, Solvay directly

reimbursed doctors for attending or presenting at CMEs by paying the seminar's cost and in some cases travel and lodging fees as well.

(X) Unrestricted Educational Grants

175. Solvay field sales representatives rewarded physicians with unrestricted educational grants in exchange for prescribing its drugs. The procedure for requesting such checks was simple; representatives used the company's standard check request form, checked the box for grants and honoraria, and supplied the physician's name and identifying information. Solvay also offered these grants to CME providers to sponsor CMEs on off-label topics regarding Solvay drugs. For example, Solvay provided support to Medical Education Resources through an unrestricted educational grant to sponsor a CME dedicated to the results of the PROGRESS trial.

ii. Non-Cash Kickback Schemes

176. In addition to the cash-for-prescriptions schemes, Solvay had other non-cash kickback schemes, as described below.

a. "Nurse Betty" Scheme

177. This was a program to promote Aceon and AndroGel that Solvay first rolled out in urban areas, with plans to expand into larger areas incrementally. Solvay would actually hire nurses to work at doctor's offices, for the sole purpose of identifying and screening patients for Solvay's drugs, primarily AndroGel. Doctors and their staff were freed from such screening, perhaps allowing them to see more patients.

b. “Stock Bottles”

178. Solvay focused its distribution of drug samples on its top prescribers. When samples were in short supply, Solvay reminded its representatives that they should reserve “stock bottles” for the top 25 or “gold” physicians. Accordingly, when Solvay ran out of FDA-approved and labeled samples, it would repackage a stock bottle of 100 pills and divide it into ten smaller packages of ten pills and give them to ten different doctors in manila envelopes, thereby violating the misbranding and labeling laws, 21 U.S.C. Sections 331(b), 352(b) & (f). The misbranding laws require that drug packages contain certain information not provided on Solvay’s manila envelopes.

c. In-Kind Gifts

179. Popular in-kind gifts in promotion of Luvox and Aceon were big game hunting trips, Harley Davidson jackets, bowling balls/shoes, spa days, and box seat tickets at sporting events. All were run through the expense department, and all were encouraged by upper management.

d. Lunch-N-Learn

180. Solvay also conducted programs called Lunch-N-Learn, where Solvay representatives would bring in food from a popular restaurant for a doctor and his staff. During the lunch, representatives would play the PROGRESS CD that contained the CME or would disseminate information on the off-label uses of Luvox, Aceon, or AndroGel.

e. Dine-N-Dashes

181. Solvay also gave doctors remuneration in the form of Dine-N-Dashes. Solvay representatives chose a popular restaurant and invited doctors to stop by to pick-up dinner. Each doctor then ordered a take-out meal for the doctor’s entire family. While the doctor waited

for the order, the sales representative gave a sales pitch on a Solvay drug. For example, on February 1, 2001, Solvay sales representatives, Stuart McCown and John Burleigh, organized a Dine-N-Dash regarding off-label uses of Aceon and AndroGel at Outback Steakhouse in Baton Rouge, Louisiana, for approximately 50 prescribers. These meals were clearly for the doctor's personal benefit and conferred absolutely no benefit on patients.

182. Solvay frequently purchased Dine-N-Dashes from expensive restaurants. For example, on one evening, Solvay spent \$300 per doctor on a Dine-N-Dash. On two other separate occasions, Solvay spent \$266.00 per doctor on a Dine-N-Dash. Solvay spent anywhere from \$150-\$300 per doctor in giving the doctors and their families meals at these Dine-N-Dashes. Dine-N-Dashes were popular forms of remuneration at Solvay because "they [] worked in a big way in the Houston district."

f. Book-N-Dash

183. Similarly, Solvay representatives gave remuneration in the form of Book-N-Dashes. Solvay representatives would invite doctors to stop by a bookstore. Each doctor then received a gift certificate to the store. While the doctor waited for the certificate, the sales representative gave a sales pitch on a Solvay drug. For example, Solvay sales representative Shannon Z. hosted a Book-N-Dash at a Barnes & Noble in Wilmington, North Carolina on February 19, 2000, spending an estimated \$500.

g. Flowers in a Flash

184. Solvay gave remuneration in the form of flowers in this scheme. A Solvay sales representative would offer physicians free flowers at a local flower shop, particularly around

special holidays, such as Valentine's Day. When the physicians came to pick up the flowers, the sales representative would take the time while the physician was waiting to promote off-label uses of Solvay drugs. These were popular schemes with physicians.

h. Gift Certificates

185. Solvay also gave doctors remunerations in the form of gift certificates. The American Medical Association ("AMA") guidelines forbid doctors from accepting gifts of substantial value (i.e. more than \$100). Solvay was aware of and had even adopted those guidelines, informing its employees that compliance with the guidelines was mandatory. But in complete disregard of the alleged company policy and the AMA guidelines, Solvay induced doctors to prescribe Solvay's drugs by seducing them with gift certificates to their favorite stores valued well above the \$100 limit.

186. Some examples of gift certificates offered in Texas are typical of the nationwide practice. Solvay representatives gave Houston doctors gift certificates to restaurants in the amounts of \$200, \$300 and \$625. Similarly, an Austin representative gave a doctor a \$203 gift certificate to a sporting goods store, Academy Sports & Outdoors. Particularly egregious, however, were the gift certificates for limousine rides in Houston and Dallas worth up to \$700. Solvay's practice of giving doctors gift certificates was plainly an attempt to pay for goodwill and induce doctors to prescribe Solvay's drugs.

i. Custom Gifts

187. To induce more prescriptions, Solvay blatantly bestowed upon doctors personal items, often geared towards the doctor's specific interests or hobbies. Solvay frequently gave doctors tickets to entertainment events. Indeed, representatives would send doctors a photocopy of event tickets with a note stating that the tickets were available if the doctor would listen to the

representative's pitch for two minutes. Thus, one Beaumont representative gave a doctor \$930 worth of Houston Astros tickets, while a Houston representative gave a doctor \$300 worth of Astros tickets.

188. Similarly, Solvay representatives gave doctors a variety of expensive personal gifts ranging from spa packages, artwork, trips, golf equipment, hunting supplies, and coupons (to Starbucks and Blockbuster, among other stores). These gifts are just some of the remuneration Solvay paid in exchange for prescriptions.

189. In addition, to the schemes described above, Solvay also put on all manner of events at restaurants, bookstores, and other venues at which physicians received gift certificates, dinners, meals to take home to their families, wine, and other gifts. Generally, all of these gifts would afford representatives the opportunity to talk to a doctor about a drug and its (off-label) uses. To obtain a Books-A-Million gift certificate, for instance, doctors had to go to the bookstore on a given day on which the event was held, and speak with the representative.

D. Solvay's Promotion of ICD-9 to Obtain Reimbursement for Luvox, Aceon and AndroGel

190. Solvay compiled comprehensive lists of SSRI, cardiovascular, urogenital, and miscellaneous "related" ICD-9 diagnosis codes that it provided to doctors for the sole purpose of concealing actual uses in order to obtain reimbursement for Luvox, Aceon and AndroGel, causing Medicaid, Medicare, CHAMPUS/TRICARE, CHAMPVA, Federal Employees Health Benefit Plan, ADIS Drug Assistance Programs ("ADAPs"), and other federal healthcare programs to reimburse for drugs that were medically unnecessary. Solvay management, including Ann Wilmoth, Solvay's Vice President of Sales, and James Prasch, Solvay's National Sales Director of Primary Care, mandated the promotion of these false codes by all field sales

representatives. For example, in an e-mail dated January 24, 2001 discussing the use of ICD-9 codes to obtain reimbursement for AndroGel, manager Kate Robertson wrote to Doe that “The best codes are the ones that reflect the symptoms, not the disease. . . .” Similarly, Jim Maxson, Regional Account Manager for Solvay, issued a memorandum providing a list of ICD-9 codes that sales representatives could offer as solutions to help achieve reimbursement for Aceon. In addition, several Illinois representatives discussed their success with the ICD-9 scheme during a presentation. Eric McGinty stated that Dr. Tiwari, a Kankakee, Illinois nephrologist, had successfully used the 585 chronic renal failure code for Medicaid patients to allow patients to continue on Aceon and to start new patients on Aceon. McGinty further stated that the nurse in Dr. Tiwari’s office appreciated his willingness to fill out preauthorization forms for her use.

191. Solvay trained its sales representatives to distribute these codes to physicians, and other practitioners with prescribing privileges, and aggressively recommend their usage. Solvay sales representatives then coached physicians to submit these alternative diagnoses to Medicaid, Medicare, CHAMPUS/TRICARE, CHAMPVA, Federal Employees Health Benefit Plan, ADIS Drug Assistance Programs (“ADAPs”), and other federal healthcare programs, suggesting codes for isolated symptoms and demonstrating with sample prescriptions.

192. Solvay also encouraged its sales representatives to provide reasons for use of a non-formulary drug to aid physicians in filling out prior authorization forms. For example, Louisiana sales representatives were encouraged to inform doctors that they could reference the PROGRESS study in the field on the prior authorization form asking for a reason for the use of a non-formulary, or non-preferred drug, when prescribing Aceon. An August 2002 e-mail from Stanley Ferrell, Solvay Channel Account Executive for Eastern United States, warned

Louisiana's sales team that Louisiana Medicaid did not approve Aceon for the preferred drug list and physicians were now required to submit prior authorization requests when prescribing Aceon. Ferrell suggested that the team inform doctors that they could reference the PROGRESS study in the field on the prior authorization form asking for a reason for the use of a non-formulary, or non-preferred drug, when prescribing Aceon.

E. Retaliation Against King and Doe

193. King and Doe met when they both worked as District Sales Managers for Solvay. Each was responsible for supervising sales representatives who marketed Luvox, Aceon and AndroGel. In these positions, King and Doe were encouraged by Solvay executives to promote the use of off-label marketing campaigns for all three drugs. Both King and Doe were terminated by Solvay after questioning Solvay's practices.

i. John King

194. In late 2001, King was encouraged by Solvay executives to develop an off-label campaign for AndroGel. In response, he suggested enlisting local urologists to lecture about the off-label uses of AndroGel to primary care physicians. Soon afterward, overworked and increasingly unsure of the ethics and legality of the off-label promotions, King started asking questions at the National Business Meeting held in January 2002 in Las Vegas, Nevada. King discussed the issue of payments and gifts to doctors in exchange for Aceon prescriptions and whether rewarding sales representatives that engaged in this type of illegal conduct was appropriate. King discussed these issues with Hynd and Steve Jennings (Director of Cardiovascular Marketing), both of whom refused to comment. Throughout January and February of 2002, King discussed Solvay's illegal marketing activities regarding several of Solvay's drugs, including Aceon and AndroGel, with several Solvay executives, including Jim

Prasch, National Sales Director for Solvay, and Christa Townsend, a Regional Business Director and King's immediate supervisor.

195. At the same time that King was voicing his dissatisfaction with Solvay's illegal marketing practices, King also discussed a health problem with a Human Resources representative at Solvay and the possibility of taking an "extended medical leave" as provided by Solvay, although King did not take leave. On April 18, 2002, King's physician declared him "unfit to work," and King planned to take extended sick leave. He was denied this opportunity, however, when Solvay terminated him later the same day for supposedly being in possession of altered marketing materials. The allegedly unapproved materials contained a presentation on the ADAM questionnaire—materials that were actually approved by King's supervisors, Townsend and Kevin Porath, Regional Marketing Manager for Solvay. Solvay claimed that King's reversal of two questions within the ADAM questionnaire made the materials unapproved, even though the reversal had no effect on the questionnaire.

196. Since his termination, King has been unable to find a position in the pharmaceutical industry.

ii. Jane Doe

197. Shortly after King's termination in April 2002, Doe complained to her supervisor, Christa Townsend, that she believed King had been wrongfully terminated and that his termination was based on something more than the reasons they had stated. She also complained that such a reason for termination, if legitimate, could put numerous people in danger of losing their jobs, including higher level, home office personnel for doing or implementing the same activities. In addition, Doe spearheaded a campaign to garner letters of recommendation for King. As a result, King was sent no less than ten letters from Solvay employees.

198. On July 23, 2002, Doe notified Solvay benefits representative Linda Hagood that she would be taking maternity leave with a projected return to work date of October 18, 2002. On July 25, 2002, Doe went on maternity leave for the birth of her child. On August 2, 2002, Doe participated as instructed, although on maternity leave, in a mandatory telephone conference for all Southwest District Managers led by James Prasch and Debbie Kishton, a Solvay Human Resources consultant. Typically, Solvay did not permit employees on leave to participate in such activities, but Kishton specifically requested that Doe stay on the line because the information was pertinent to her. Kishton and Prasch informed the district managers that any communication with a departed employee could be detrimental and damaging and could result in unfavorable legal action against Solvay. They also informed them not to offer recommendations and particularly to avoid using Solvay letterhead.

199. Concerned about the ramifications to the company, Doe immediately contacted Kishton and told her that she had been in verbal and written contact with King and had provided him with a written recommendation on Solvay letterhead to assist him in his job search.

200. Shortly after the August conference call, Doe felt pressure to return from maternity leave early. On August 19, 2002, Doe e-mailed Townsend and Hagood that she intended to return to work from maternity a month earlier in mid-September as opposed to her original plan to return on October 18, 2002. Hagood asked Doe about this decision. Doe explained to Hagood that she felt that upper management was taking over her job and that she thought her job was in jeopardy.

201. While she was on leave in September 2002, Doe learned from a sales representative under her supervision that Townsend had held a telephone conference call on

September 3, 2002, with all of the sales representatives in her region to discuss the marketing campaigns. When Doe asked Townsend about the call, Townsend told Doe that she could not participate in the call. Townsend also indicated that she could not provide Doe with any further information about the call because Doe was still on a leave of absence. Suspicious of Townsend's behavior and reasoning, Doe spoke with a sales representative on her team and learned that Solvay was investigating her for engaging in unapproved off-label marketing.

202. Worried that her job was in jeopardy, Doe began asking Townsend and the Solvay Human Resources department what was happening and if she could offer any input. On September 5, 2002, Solvay locked Doe out of her voicemail and e-mail. Doe learned from a sales representative on her team that Townsend had asked the sales representatives not to speak with Doe. When Doe questioned the Human Resources department about what was happening, she was told that she would need to obtain a physician's release to return to work before any information would be shared with her. Doe obtained a letter from her physician releasing her to return to work on September 5, 2002. The next day, Mark Banks in Solvay's Human Resources department and Townsend notified Doe that she was suspended with pay while they conducting an investigation regarding unapproved marketing materials.

203. From September 13, 2002 through September 16, 2002, Doe had various conversations with Townsend and others regarding their allegations of wrongdoing. Doe also provided documentation demonstrating that her actions amounted to common practice. On September 17, 2002, Doe met with Townsend and Kathy Frankel, a Solvay Human Resources representative. After reviewing all of the materials that Doe had sent in support of her actions, Frankel notified Doe at the meeting that she was terminated.

VII. ACTIONABLE CONDUCT BY SOLVAY UNDER THE FALSE CLAIMS ACT

A. Applicable Law

i. The False Claims Act

204. This is an action to recover damages and civil penalties on behalf of the United States and Relators King and Doe arising from the false or fraudulent statements, claims, and acts by Solvay made in violation of the False Claims Act, 31 U.S.C. §§ 3729–3732.

205. For conduct occurring before May 20, 2009, the False Claims Act (“FCA”) provides that any person who:

- (a) knowingly presents, or causes to be presented, to an officer or employee of the United States Government or a member of the Armed Forces of the United States a false or fraudulent claim for payment or approval;
- (b) knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the Government;
- (c) conspires to defraud the Government by getting a false or fraudulent claim allowed or paid;
- (d) knowingly makes, uses, or causes to be made or used, a false record or statement to conceal, avoid, or decrease an obligation to pay or transmit money or property to the Government

is liable to the Government for a civil penalty of not less than \$5,500 and not more than \$11,000 for each such claim, plus three times the amount of damages sustained by the Government because of the false or fraudulent claim.

206. For conduct occurring on or after May 20, 2009, the FCA provides that any person who:

- (a) knowingly presents, or causes to be presented a false or fraudulent claim for payment or approval;

- (b) knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim (except that this language applies to all claims pending on or after June 7, 2008)
- (c) conspires to defraud the Government by committing a violation of the FCA;
- (d) knowingly makes, uses, or causes to be made or used, a false record or statement to conceal material to an obligation to pay or transmit money or property to the Government

is liable to the Government for a civil penalty of not less than \$5,500 and not more than \$11,000 for each such claim, plus three times the amount of damages sustained by the Government because of the false or fraudulent claim.

207. The FCA allows any persons having knowledge of a false or fraudulent claim against the Government to bring an action in federal district court for themselves and for the United States Government and to share in any recovery as authorized by 31 U.S.C. § 3730.

208. Based on these provisions, Relators King and Doe, on behalf of the United States Government and the States of California, Delaware, Florida, Georgia, Hawaii, Illinois, Indiana, Louisiana, Michigan, Montana, Nevada, New Hampshire, New Jersey, New Mexico, New York, Oklahoma, Rhode Island, Tennessee, and Texas, the Commonwealths of Massachusetts and Virginia, and the District of Columbia (collectively the “states”) seek through this action to recover damages and civil penalties arising from Solvay’s causation of the submission of false claims to the federal and state governments. In this case, such claims were submitted to the federal and state governments for payment for Solvay’s drugs, Luvox, Aceon, and AndroGel. Relators believe that the United States and the states have suffered significant damages as a result of false claims for payment for Luvox, Aceon, and AndroGel.

209. There are no bars to recovery under 31 U.S.C. § 3730(e), and, or in the